

AWARD NUMBER: **W81XWH-15-1-0032**

TITLE: **Effectiveness of a Driving Intervention on Safe Community Mobility for Returning Combat Veterans**

PRINCIPAL INVESTIGATOR: Sandra Winter

CONTRACTING ORGANIZATION: **University of Florida**
Gainesville, FL 32611

REPORT DATE: **May 2018**

TYPE OF REPORT: **Annual**

PREPARED FOR: **U.S. Army Medical Research and Materiel Command**
Fort Detrick, Maryland 21702-5012

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13. SUPPLEMENTARY NOTES					
14. ABSTRACT This study is a follow-on to prior DOD funded work "Efficacy of a Driving Intervention Program on Safe Community Mobility for Combat Veterans". Funding for the Effectiveness (current) study was activated in October 2015. In the 2017-2018 cycle, we completed our staffing with an occupational therapist/ Certified Driving Rehabilitation Specialist in place beginning 6/1/2017. Team training was completed and subject recruitment/testing began July 2017. As of April 2018 we have 12 Veterans enrolled in the five session protocol, half randomized to the occupational therapy driving intervention (OT-DI) and half to the control arm, traffic safety education (TSE). To enhance the rigor of the testing we are ensuring that the simulator drives have an appropriate randomization of events to prevent learning effect. Simulator vendor DriveSafety completed creation of the novel drives and the versions for training and testing in November 2017. In Fall 2017, we also enhanced the traffic safety education curriculum to an up-to-date version with increased interactivity. In addition to on-going recruitment and testing, our team has been able to disseminate findings from the efficacy study on a state and national level. This includes XX publications to date (XX journal articles and one book chapter), and XX state and national level presentations. Our future directions include examining real-world driving through analysis of driver license records to determine the level of violations, citations, and crashes in the years pre and post intervention.					
15. SUBJECT TERMS Randomized Clinical Trial, Intervention, Driving, Rehabilitation, Simulation					
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Introduction

Intervention for combat veterans' driving safety requires a multi-factorial approach to address the often co-occurring effects of TBI/ PTSD/ other blast related injuries sustained by combat veterans as well as the impact of deployment experiences on their driving. Intervention provides critical information on the combat veterans' driving fitness, impact of medical and psychological conditions on driving, and driving rehabilitation needs. Effective driving interventions have potential to increase driving safety and reduce MVC and the resulting injuries and deaths. Furthermore, promoting driving fitness may also have carryover effects supporting other key arenas of community re-integration such as family functioning, employment, participation in society, and satisfaction with life. In our efficacy study we demonstrated the feasibility of our intervention, and early data suggest efficacy of the OT-DI for combat veterans with mild TBI, PTSD, and/or orthopedic conditions. The efficacy study did however have limitations including a small sample, attrition, and mostly male subjects. In our current effectiveness study we are seeking to expand our study sample, providing power for more detailed analyses of OT-DI outcomes include reduction of driving errors (measured via simulated driving evaluation), as well as real world outcomes. Ours is the first study to look at impact of an occupational therapy driving intervention on driving difficulty and driving fitness as measured in an on-road evaluation. Additional measures include proxy report of Veteran driving difficulty, and violations, citations, and crashes based on state department of motor vehicle records.

Keywords: Randomized Clinical Trial, Intervention, Driving, Rehabilitation, Simulation

ACCOMPLISHMENTS

- Initiated recruitment in July 2017, following hiring and training of Research Therapist, Dr. Luther King, DrOT and Certified Driving Rehabilitation Specialist
- Enrolled 12 subjects in the study
- Completed testing with 1 subject (Five sessions over a six month period)
- Have 11 subjects who are active (baseline testing/ and or additional sessions complete with future testing scheduled)
- Developed new community partners for recruitments through events.
- Outreach to VA partners across the North Florida / South Georgia VHS service area.
- Graduated one VA WOC status Bachelor of Health Science Honors student, Katelyn Caldwell with completed thesis.
- Established VA WOC status for one new BHS honors students, Kasey Clark, to work as research assistant (April 2018 to May 2019).

Impact

On principal discipline – We have been successful at dissemination of a protocol for use of the simulator as a rehabilitation tool for veterans experiencing driving difficulty. In addition to articles, and a book chapter – we have presented at national conferences including those devoted to driving rehabilitation.

On other disciplines - Several disciplines that engage in community reintegration of veterans benefit as our work complements work they are engaged with to address driving difficulty. These disciplines include but are not limited to psychology, social work, and community service coordinators. Our work also intersects with work done by VA researchers on unintentional injury and prevention.

On technology transfer - The newly created simulator drive content is Veteran-centric, addressing driving difficulties unique to this population. Development of this content now makes it available to multiple military and VA sites using the DriveSafety simulators for rehabilitation.

On society – A desired outcome of this work would be, that by addressing driving difficulty in post-deployed veterans, they would be more mobile within their communities. In addition, by reducing driving errors we expect that veterans will have a greater level of safety, and a reduced burden of crashes, unintentional injury, and other negative sequelae.

Changes/Problems

- Revised project's Principal Investigator position; Dr. Sherrilene Classen assumes PI role while Dr. Winter is now a Co-Investigator. See IRB approval in Appendices.
- Updated protocol details regarding traffic safety education curriculum provision through Driver Training Associates via on-line Florida Department of Highway Safety and Motor Vehicle approved Basic Driver Instruction computer-based interactive course. This was not a significant change to protocol as the core content remains the Florida Department of Highway Safety and Motor Vehicle approved Basic Driver Instruction curriculum and video-intensive instruction. Change was necessary as Safety Council vendor was unable to provide an updated version.

Products

Our scope includes data analysis from “Efficacy of a Driving Program on Safe Community Mobility for Combat Veterans (W81XWH-11-1-0454)”. Below find publications and presentations to date including publications* from 2017-2018 cycle.

Publications:

- *Classen, S., & Winter, S.M. (2017). Chapter 16. Driving performance of returning combat veterans. In S. Classen (Ed.), *Driving simulation for assessment, intervention, and training: A guide for occupational therapy and health care professionals* (187-199). Bethesda, MD: AOTA Press.
- *Classen, S., Winter, S.M., Monahan, M., Lutz, A., Platek, K., & Yarney, A. (2017). Driving intervention for returning combat veterans: Interim analysis of a randomized controlled trial. *OTJR: Occupation, Participation and Health*, 37(2), 62-71. doi:10.1177/1539449216675582
- *Caldwell, K. (2017). Implementing Traffic Safety Education in a Randomized Controlled Trial for Combat Veterans. (Bachelor of Health Science Honor thesis). University of Florida, Gainesville, Florida.
- Winter, S. M., Sursky, S., Classen, S, Yarney, A., Monahan, M., Platek, K., Lutz, A. L., Levy, C. (2016). Intermediate term effects of an occupational therapy driving intervention for combat veterans. *American Journal of Occupational Therapy*, 70(4_Supplement_1):7011515253p1.
- Winter, S. M., Szafranski. E., Classen, S, Yarney, A., Monahan, M., Platek, K., Lutz, A. L., Levy, C. (2016). Combat veterans’ strategies to manage risky driving and preferences for driving intervention. *American Journal of Occupational Therapy*, 70(4_Supplement_1):7011515253p1.
- Classen, S., Yarney, A. K. A., Monahan, M., Winter, S. M., Platek, K., & Lutz, A. L. (2015). Rater reliability to assess driving errors in a driving simulator. *Advances in Transportation Studies, an International Journal*.
- Classen, S., Monahan, M., Canonizado, M., & Winter, S.M. (2014). An Occupational Therapy Driving Intervention’s Utility for a Combat Veteran. *American Journal of Occupational Therapy*, 68(4), 405-411.
- Miller, K. (2015) Combat Veteran Community Integration in a Driving Intervention. (Honor thesis).
- Sursky, S. (2015). Intermediate Term Effects of an Occupational Therapy Driving Intervention for Combat Veterans. (Honor thesis).
- Szafranski, E. (2015). Understanding Combat Veterans Perspectives on Strategies to Manage Unsafe Driving and Preferences for Driving Intervention. (Honor thesis).
- McGowan C. (2014). Combat Veterans’ Perspectives on Driving Strategies to Curtail Unsafe Driving. (Honor thesis).

Presentations:

Classen, S., Winter, S. M., Jeghers, M., & Caldwell, K. Workshop. Mixed-Methods Approach to Develop an Occupational Therapy Driving Intervention for Returning Combat Veterans. FOTA Conference, Orlando, Florida, USA November 3-4, 2017.

Classen, S., & Winter, S. M. Research Paper. Interim Findings of a RCT: Driving Intervention for Returning Combat Veterans. AOTA Conference, Salt Lake City, Utah, USA, April 19-22, 2018.

Classen, S., Winter, S., Yarney, A., & Levy, C. Driving Intervention for Returning Combat Veterans: Interim Analysis of a RCT. 6th Occupational Therapy Summit of Scholars, Boston University, Boston, MA, USA, June 2-June 3, 2017.

Classen, S., Winter, S. M., Levy, C., Yarney, A., & Monahan, M. Driving intervention for returning combat veterans: Interim analysis of a randomized controlled trial. Poster presented at the AOTA Conference, March 30 – April 2, 2017, Chicago, Illinois.

Winter, S. M., Classen, S., Reid, E. Grounded theory on factors influencing driving of combat veterans post-deployment. Presentation given at the 6th Occupational Therapy Summit of Scholars, June 2-3, 2017, Boston University, Boston, Massachusetts.

Winter, S. M., Szafranski, E., Classen, S., McGowan, C., Levy, C., Monahan, M., & Yarney, A. Grounded theory focus group findings in combat veteran with driving performance issues. Poster presented at the AOTA Conference, March 30 – April 2, 2017, Chicago, Illinois.

Szafranski, E., Winter, S. M., Classen, S., Yarney, A., & Levy, C. Combat veterans' strategies to manage risky driving and preferences for driving intervention. Poster presented at the AOTA Conference, April 7, Chicago, Illinois.

Sursky, S., Winter, S. M., Classen, S., Yarney, A., Monahan, M., Lutz, A., Platek, K., & Levy, C. Efficacy of a simulator-based occupational therapy driving intervention for returning combat veterans. Poster presented at the AOTA Conference, April 7, 2016, Chicago, Illinois.

Szafranski, E., Winter, S. M., Classen, S., Yarney, A., & Levy, C. Combat veterans' strategies to manage risky driving and preferences for driving intervention. Poster presented at the FOTA 2015 Fall Conference, Nov 6-7, Kissimmee, Florida.

Sursky, S., Winter, S. M., Classen, S., Yarney, A., Monahan, M., Lutz, A., Platek, K., & Levy, C. Efficacy of a simulator-based occupational therapy driving intervention for returning combat veterans. Poster presented at the Florida Occupational Therapy Association's 2015 Fall Conference, Nov 6-7, Kissimmee, Florida.

Winter, S. M., Special populations/conditions: Returning combat veterans. Presented at the 39th Association for Driving Rehabilitation Specialists (ADED) Annual Conference. Louisville, Kentucky, August 1, 2015, as part of the symposium "Driving Simulation: Sharing evidence, enhancing practice" (Classen, S. – lead author/ moderator).

Szafranski, E., Winter, S. M., Classen, S., & Levy, C. Combat veterans' strategies to manage risky driving and preferences for driving intervention. Poster presentation - 39th Annual Assoc. for Driving Rehabilitation Specialists Conference. Louisville, KY, August 1, 2015

Sursky, S., Winter, S. M., Classen, S., Yarney, A., Monahan, M., Lutz, A., Platek, K., & Levy, C. Intermediate-term effects of an occupational therapy driving intervention for combat veterans. Poster presented at the 39th annual Association for Driving Rehabilitation Specialists (ADED) Annual Conference. Louisville, Kentucky, August 2, 2015.

Winter, S. M., Classen, S., Levy, C., Yarney, A., Monahan, M. Sursky, S., and Szafranski, E. Efficacy of a driving intervention for Veterans with polytrauma using a simulator. Poster presented at the VA RR&D Polytrauma conference "New Perspectives in TBI Rehabilitation". Hyattsville, Maryland, May 5-6, 2015.

Cormack, N., Classen, S., Monahan, M., Winter, S.M., Yarney, A., Lutz, A., Platek, K., & Levy, C. Efficacy of an occupational therapy driving intervention for OEF/OIF combat Veterans: A pilot study. Poster presented at the 95th American Occupational Therapy Association Annual Conference. Nashville, Tennessee, April 18, 2015.

Participants and other collaborating organizations

Veterans Affairs is a collaborator on this study with involvement of both the Center of Innovation on Disability and Rehabilitation Research, a VA Center of Innovation, and the North Florida/ South Georgia Veterans Health System. The VA provides infrastructure and support for the investigators, material resources such as the simulator, use of VA facilities for recruitment and testing, and research oversight.

During this year, the following persons were active on the project:

Name: Sherrilene Classen, PhD, MPH, OTR/L, FAOTA, FGSA

Project Role: PI as of March 2018 IRB approval

Researcher Identifier (e.g., ORCID ID):

Nearest person month worked: 3

Contribution to Project: Dr. Classen contributed her expertise in clinical trials, guiding study design and implementation, and planning and overseeing the analyses in conjunction with the PI, the biostatistician and co-investigators. Dr. Classen contributed extensively to the development of manuscripts, the submission of presentations, dissemination of findings, and development of future proposals to extend the work.

Funding Support: N/A

Name: Sandra Winter, PhD, OTR/L

Project Role: PI until March 2018, Co-I after March

Researcher Identifier: orcid.org/0000-0002-0317-241X

Nearest person month worked: 6

Contribution to Project: Dr. Winter had overall responsibility for the project execution. She organized the research team and oversaw main research functions. Thus, appoint research staff, obtain IRB approval, manage developmental activities and research activities, collaborate with the project personnel, consultant(s), and the developer of the DriveSafety 250 driving simulator. She supervised the research coordinator, research therapist and research assistants, oversaw data collection, analysis and interpretation, and developed manuscripts, research presentations and reports.

Funding Support: N/A

Name: Charles Levy, MD

Project Role: Co-I

Researcher Identifier (e.g., ORCID ID):

Nearest person month worked: 1

Contribution to Project: Dr. Levy's functions as a co-investigator include assisting with recruitment, guiding interaction with VA partners, and educating the team on the rehabilitation needs of the returning combat Veterans. He will participate in recruitment of participants, interpretation of the results, outcome dissemination, and translation of study findings to VA health care settings.

Funding Support: Dr. Levy is a VA physician, salary (5% effort) is paid by VA.

Name: Michael Marsiske, PhD

Project Role: Co-I

Researcher Identifier (e.g., ORCID ID):

Nearest person month worked: 1

Contribution to Project: Dr. Marsiske will collaborate with the team and the biostatistician on data analyses to look at the contribution of the evaluation battery to predicting real world driving performance. He will assist in development of study design, recruitment, and outcomes dissemination.

Funding Support: N/A

Name: Abraham Yarney, M.E.

Project Role: Graduate Student

Researcher Identifier (e.g., ORCID ID): N/A

Nearest person month worked: 6

Contribution to Project: Primary functions are preparation of study materials for recruitment and testing, recruitment, and data entry. Secondary functions are data management, data audits (with PI), and data analysis overseen by the team and the biostatistician.

Funding Support: N/A

Name: Mary Jeghers, MSOT, OTR/L

Project Role: Graduate Student

Researcher Identifier (e.g., ORCID ID): N/A

Nearest person month worked: 3

Contribution to Project: Primary functions are preparation of study materials for recruitment and testing, distribution of recruitment materials, and data entry. Secondary functions are data management, data audits (with PI), and analysis of data as overseen by the team and the biostatistician.

Funding Support: N/A

Name: Shabnam Medhizadah, MS

Project Role: Graduate Student

Researcher Identifier (e.g., ORCID ID): N/A

Nearest person month worked: 2

Contribution to Project: Primary functions are preparation of study materials, screening participants, recruitment, and participant payment.

Funding Support: N/A

Name: Katelyn Caldwell, BHS student (Graduated on May 5, 2018)
Project Role: Honors Student / Research Assistant
Researcher Identifier (e.g., ORCID ID): N/A
Nearest person month worked: 3
Contribution to Project: Primary functions are preparation of study materials for recruitment and testing, distribution of recruitment materials, and data entry.
Funding Support: N/A

Name: Kasey Clark, Bachelor of Health Science Honors student
Project Role: Honors Student / Research Assistant
Researcher Identifier (e.g., ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Primary functions are preparation of study materials for recruitment and testing, distribution of recruitment materials, and data entry.
Funding Support: N/A

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Dr. Winter has no new funded projects.

Dr. Sherrilene Classen assumed PI role following IRB approval this spring. Her current support is listed below:

US Department of Defense **Classen (PI)** 4/15/2015 – 4/14/2019
(effective March 2018)
Effectiveness of a Driving Intervention on Safe Community Mobility for Returning Combat Veterans
Goal: To conduct an effectiveness trial with returning combat veterans.

AAA **Classen (PI)** 08/01/2017-12/31/2018
Smart Features for Older Drivers Version 3
Goal: Update the Smart Features initiative to include classifying the benefits of in-vehicle and automated vehicle technologies for older drivers.

NIH (NCMRR) K-12 **Ottenbacher (PI)** 09/01/2017-08/31/2022
Rehabilitation Research Career Development Programs (RRCD)
Goal: The RRCD educates and trains future rehabilitation scientists in occupational and physical therapy.
Role: Associate Program Director, Executive Committee, University of Florida

HUD CFDA# 14.536 **Ahrentzen (PI)** 09/01/2017-08/31/2020
Goal(s): (1) Develop and test repurposed fixtures and interior layouts of prototypical SSAH for accessibility, cost and attractiveness, for different occupant types. Determine the most effective means to convey findings as a decision support tool to a variety of potential users.
Role: Co-PI (Classen)

Florida Department of Transportation CP 18-04-11 Classen (PI) 10/01/2017-09/30/2018
Aging Road User Information Systems
Goal: To enhance the Florida Senior Safety Resource Center's database with GIS mapping.

Florida Department of Transportation Highway Safety DD-18-04-01/G0Q23 Cahill (PI)

10/01/2017- 09/30/2018

Teen Distracted Driving Education Program

Goal: Develop a computer based training program to reduce distracted driving in teens.

Role: Co-PI (Classen)

Department of Veteran's Affairs

Ahrentzen (PI)

04/02/2018-

06/30/2019

Testing CODY

Goal: Testing an immersive technology tool for experiencing and assessing home modifications for veterans with movement disabilities and disorders.

Role: Co-PI

What other organizations were involved as partners?

1) Organization Name: Veteran Affairs / North Florida – South Georgia VHS

Location of Organization: Gainesville, Florida

Partner's contribution to the project:

- Financial support provided for Dr. Levy's salary and expenses for simulator van (insurance, fuel and maintenance)
- In-kind support is provided through use via revocable license of two DriveSafety simulators
- Facilities support includes use of office space at Center of Innovation on Disability and Rehabilitation Research (CINDRR) and the use of NF/SG VA facilities for recruitment and testing
- Collaboration includes networking with CINDRR team and clinical staff of VA
- Additionally the VA provides the medical monitor for the study and VA Research Office staff review the study and oversee compliance once initiated.

Special Reporting – Quad Chart

Appendices.

A: IRB approval change of PI to Sherrilene Classen

B: CONSORT diagram/Flowchart of Subject and Proxy Enrollment (as of May 2018)

C: Products

- a) Publications
- b) Presentations

Effectiveness of a Driving Intervention on Safe Community Mobility for Returning Combat Veterans



Award Number – W81XWH-15-1-0032

PI: Classen, Sherrilene

Org: University of Florida

Award Amount: \$1,781,608

Study/Product Aim(s)

Specific Aim 1. Enhance the OT-DI with development of targeted simulator drives addressing CV driving triggers and assess user satisfaction (n=30)

Specific Aim 2. Evaluate group differences among the OT-DI group and the traffic safety education group measuring at baseline, post-intervention and three months post-intervention: (a) the type and number of driving errors made on a simulator, (b) CV and caregiver rating of driver difficulty, and (c) archival records, i.e. state-recorded violations, citations, and crashes. (n=180 Veterans and 150 Caregivers)

Specific Aim 3. Determine effectiveness of the OT-DI, specifically addressing the impact of the OT-DI vs. traffic safety education in reduction of total driving errors and critical driving errors such as speeding measured during simulated driving.

Specific Aim 4. Examine the impact of the OT-DI and traffic safety education on real-world driving in a sub-set of CVs (n=30) using on-road testing.

Approach: Effectiveness study of a clinical intervention using a repeated measures design.



Accomplishment: We have been actively testing subjects since Fall 2017, with 12 enrolled subjects (6 each arm). Simulator drives/ new scenarios are integrated. An OT – Certified Driving Rehabilitation Specialist was hired, trained, and is providing OT-DI. Team had two publications and multiple presentations (including state/ national).

Timeline and Cost

Activities	CY	14	15	16	17
Aim 1. Refine intervention					
Aim 2. Evaluate group differences					
Aim 3. Examine tx effect simulator					
Aim 4. Examine tx effect real-world driving					
Estimated Budget (\$K)		\$518	\$450	\$462	\$415

Goals/Milestones

CY14 Goal – Refine intervention

- ☐ Complete user evaluation of simulator drives and integrate into intervention

CY15 Goals – Evaluate group differences

- ☐ Compare type and number of errors made on simulator
- ☐ Analyze CV and caregiver rating of driver difficulty (pre/post)

CY16 Goal – Examine treatment effect in simulator

- ☐ Determine effectiveness of the OT-DI, specifically addressing the impact of the OT-DI vs. traffic safety education

CY17 Goal – Examine treatment effect on real-world driving

- ☐ Analyze archival records, i.e. state-recorded violations, citations, and crashes

Comments/Challenges/Issues/Concerns

- We expect retention of subjects to be our biggest challenge and have a multi-faceted plan to reduce attrition across sessions

Budget Expenditure to Date : \$371,700 as of 4/15/2018

Updated: 4/23/2018



Health Center Institutional Review Board
FWA00005790

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Gainesville FL 32610-0173
Telephone: (352) 273-9600
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DATE: 3/8/2018
TO: Sherrilene Classen
PO BOX 100164
Gainesville, Florida 32610-0164
FROM: Peter Iafrate, IRB Chairman, University of Florida
Chair IRB-01
IRB#: **Revision 10 for IRB Study #IRB201500871**
TITLE: Effectiveness of a Driving Intervention on Safe Community Mobility for Returning Combat Veterans

Revision Approved - Full Board

On **3/7/2018**, the IRB reviewed and approved your revision:

[Revision 10 for IRB Study #IRB201500871](#)

Approval Includes, but is not limited to:

Principal Investigator: Revised from Sandra Winter to Sherrilene Classen

Study Staff: Added Sandra Winter (Co-Investigator/PI Proxy)

Dated and watermarked IRB-approved Informed Consent Form(s):

- Intervention testing PI Version dated 12/13/2016: Updated Study Staff
- Usability Evaluation PI Version dated 12/13/2016: Updated Study Staff
- Caregiver PI Version dated 12/13/2016: Updated Study Staff

Revised Protocol PI Version dated 12/15/2016:

- Investigators: Updated PI from Sandra Winter to Sherrilene Classen
- Study Team Roles and Responsibilities: Updated roles for Sandra Winter and Sherrilene Classen

Research-only Procedures: Updated RAC Form

Recruitment Methods Updated:

- 2nd Study Flyer
- Recruitment PowerPoint
- Telephone-Scrip Caregiver
- Telephone-Scrip Combat Veteran

VA Research: Updated Addendum V and HIPAA Authorization

Thank you for keeping the IRB informed about your research project, thereby allowing us to keep accurate files.
If the IRB staff can be of any further assistance, please feel free to call.

Study Team:

Michael	Marsiske	Co-Investigator
Luz	Semeah	Other
David	FitzGerald	Other
Sandra	Winter	Co-Investigator
Mary	Jeghers	Other
Abraham	Yarney	Study Coordinator
Charles	Levy	Co-Investigator
Shabnam	Medhizadah	Other
Luther	King	Other
Katelyn	Caldwell	Other
Babette	Brumback	Co-Investigator

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Protocol

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1. Project Title:

Effectiveness of a Driving Intervention on Safe Community Mobility for Returning Combat Veterans

Funding provided by the Department of Defense (DOD) as part of the Congressional Directed Medical Research Program

2. Investigator(s):

PI: Sherrilene Classen, PhD, MPH, OTR/L, FAOTA, FGSA
University of Florida, P.O. Box 100164, Gainesville, FL 32610, phone 352-273-6883, fax 352-273-6048, sclassen@phhp.ufl.edu

Study Team Roles and Responsibilities:

Principal Investigator – Sherrilene Classen, PhD, MPH, OTR/L, FAOTA, FGSA, is Professor and Chair, Department of Occupational Therapy, University of Florida, Florida. - Dr. Classen will have overall responsibility for the project execution. She will organize the research team and oversee all the main research functions. Thus, appoint research staff, obtain IRB approval, manage developmental activities and research activities, collaborate with the project personnel, and consultants. She will supervise the Research Assistant, oversee data collection, analysis and interpretation, and develop manuscripts, research presentations and reports. She will conduct weekly team meetings to ensure successful execution of the tasks and completion of milestones. Dr. Classen will have the primary responsibility for IRB and human subject protection matters. She will network with other sites OEF/OIF service delivery sites to increase our recruitment of CV. Dr. Classen will complete all qualitative data collection and analysis, participate in manuscript writing, other forms of data dissemination and future grant applications.

Co-Investigator – Dr. Sandra Winter, PhD - Adjunct Research Assistant Professor in the Department of Occupational Therapy, Associate Director of the University of Florida's Institute for Mobility, Activity, and Participation (I-MAP), and a Health Science Specialist at the Veterans Affairs' Center for Innovation in Disability and Rehabilitation Research (CINDRR) – North Florida/South Georgia Veterans Health System. Dr. Winter will contribute her expertise in clinical trials, implementation, and planning and overseeing the analyses in conjunction with the PI, the biostatistician and co-investigators. Dr. Winter will contribute extensively to the development of manuscripts, the submission of presentations, dissemination of findings, and development of future proposals to extend the work.

Co-Investigator - Charles Levy, MD, North Florida/ South Georgia Veteran's Health System and Rehabilitation Outcomes Research Center (RORC) - Dr. Levy's main function will be that of referring physician. Dr. Levy will participate in research meetings; and council team members on the clinical issues of each of the CV referred to this study. He will participate in recruitment of participants, interpretation of the results, and in outcome dissemination.

Co-investigator – Michael Marsiske, PhD - Associate Professor in the Department of Clinical & Health Psychology, and a faculty associate in the University's Institute on Aging. Dr. Marsiske's role on this project includes contributing his extensive expertise in cognitive psychology toward interpretation of the results and refinement of the occupational therapy driving intervention. His experience Dr. Marsiske will collaborate with the team and the biostatistician on data analyses to look at the contribution of the evaluation battery to predicting real world driving performance. He will assist in development of study design, recruitment, and outcomes dissemination.

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Co-investigator – Babette Brumback, PhD - Associate Professor in the Department of Biostatistics, UF's College of Public Health and Health Professions and in UF's College of Medicine. Dr. Brumback will help with the design of the research studies, data management; and lead the statistical analysis and computations. She will participate in the interpretation of the results, development of manuscripts and presentations, and in outcome dissemination.

Research Therapist– Luther King, PhD, Dr. King's primary responsibility for participants will include testing (baseline testing and post tests) and delivery of the occupational therapy driving intervention (OT-DI). The research therapist will also conduct any on-road testing and behind-the-wheel training needed to complete study aims, or ensure the adequate assessment and attention to participant safety. He will assist with participant recruitment, evaluation, deliver the OT-Driving intervention, conduct the pre and post-tests and provide input in manuscript writing and future grant applications.

Research Therapist x 1 (classification UF Clinical Programs Coordinator – Grade 4) –TBD, The research therapist(s) responsibilities will include assisting applications and on-going communication with all regulatory and oversight boards including UF's Institutional Review Board (IRB), the North Florida South Georgia VA Research Service, and the DoD's HRPO. The research therapist will implement the recruitment plan, assist with screening of Veterans and enrollment activities including consent. He or she will coordinate contact with all participants, maintain the study calendar and appointments, and oversee equipment use and maintenance. The research therapist will assist Dr. Classen in administration and supervision of the research therapist and the research assistant.

Graduate Research Assistant – Abraham Yarney, MS, University of Florida Department of Occupational Therapy: Primary functions will be preparation of study materials for recruitment and testing, distribution of recruitment materials, and data entry. Secondary functions will include data management, data audits (with PI), and analysis of data as overseen by the team and the biostatistician. This assistant will also complete administrative tasks to support the research therapist. The assistant will also retrieve violation, citation, crash and mishap history from the Department of Motor Vehicles and Highway Safety.

Graduate Research Assistant – Mary Jeghers, MS, University of Florida Department of Occupational Therapy. Her primary functions will include, screening study subjects, sending recruitment flyers and leading study recruitment presentations to VHS throughout North Florida and South Georgia. She will assist Dr. Winter with CPRS subject data entry. Mary will also assist with administrative tasks to support the research therapist.

Graduate Research Assistant – Shabnam Medhizadah, MS, University of Florida Department of Occupational Therapy. Shabnam Medhizadah will assist subject recruitment, subject payment, test scheduling and screening. Additionally she will assist with administrative tasks to support the research therapist.

BHS honors student – Kateyln Caldwell, University of Florida Department of Occupational Therapy. She will assist with subject recruitment and preparation study materials for subject assessment.

Consultant – Miriam Monahan, OTR/L, certified driving rehabilitation specialist (CDRS), and a certified driving instructor (CDI) - Her consultant role will be to review assessment and intervention procedures and provide training and clinical oversight for the research therapist(s). The research therapist(s) are OT-DRS's (occupational therapists-driving rehabilitation

specialists) who will receive direct training from Ms. Monahan on the study protocol, and the driving performance and intervention needs of returning combat Veterans.

Medical Monitor – David Fitzgerald, MD: - He is a qualified physician or health professional at the North Florida South Georgia VAMC, he is able to provide medical care to research volunteers for conditions that may arise during the conduct of the study, and who will monitor the volunteers during the conduct of the study. The medical monitor plays a role in reviewing serious adverse events and unanticipated problems.

The research monitor:

- may discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research;
- shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report; and,
- shall have the responsibility to promptly report their observations and findings to the IRB or other designated official and the HRPO.

Collaborating Institutions

- University of Florida Department of Occupational Therapy – primary responsibility for planning and implementation of study, provide research staff, conduct protocol, collect and analyze data (using VA RORC facilities and resources)
- North Florida/South Georgia Veterans Health System
- NF/SG VA Rehabilitation Outcomes Research Center (RORC) – RORC facilities and resources include staff offices, research space for data storage and analysis, and computer resources (secure network and IT support)
- NF/SG VAMC's Physical Medicine and Rehabilitation Clinic, OEF/OIF & Seamless Transition Program, Women's Clinic, and Community-Based Out-Patient Clinics – Participate in recruitment by informing eligible veterans of the study.

Site Information: Research activity will take place at NF/SG VHS, the University of Florida, Department of Occupational Therapy, UF Smart house at Oak Hammock, at a safe and secure location near the homes of Veteran participants in a mobile driving simulator and Community library or community center near VA participant.

The institution with regulatory authority over the research activities that transpire in this vehicle will be the NF/SG VHS. In addition, outreach sites for recruitment will include NF/SG VAMC's Physical Medicine and Rehabilitation Clinic, OEF/OIF & Seamless Transition Program, Women's Clinic, and Community-Based Out-Patient Clinics; and Wounded Warriors' TRACK Program in Jacksonville, FL.

ORP HRPO Final Approval: This protocol will be conducted in accordance with the protocol submitted to and approved by the ORP HRPO and will not be initiated until written notification of approval of the research project is issued by the ORP HRPO.

3. Abstract:

Driving is a portal into general life functioning, and impaired driving skill can pose a serious threat to the combat veterans (CV), passengers and others; and involves increased risk of subsequent injuries, medical expenses and legal sequelae. **Motor vehicle crashes (MVC)**

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among post deployed CV are one of the top four causes of injury and disability, hospitalization, and outpatient visits across the military, and are a *leading cause of death* among Army service members. The risk of MV death is significantly increased in years immediately following return from the battlefield. In sum, the effects of TBI/ PTSD/ other blast related injuries, combined with the “battlefield” mindset and lack of community reintegration programs place CV at risk for MVC and fatalities. ***The need for efficient assessments and interventions to reduce MVC post deployment has never been greater.*** On-road assessments, the gold standard, presents a risk for crash or adverse events in this population of CV. Alternately, simulated driving evaluation measures driving performance in a safe, accurate and objective manner with evidence of absolute and relative validity when compared to real world (on-road) driving. Knowing who can or cannot safely resume driving, and providing rehabilitation for those with a potential for resuming safe driving could result in: increased safe driving behaviors; avoidance of injuries, collisions, citations and their residues; and resuming safe driving with its attendant benefits in the realms of family functioning, participation in society and satisfaction with life. The overarching objective of this proposal is to discern, after clinical and simulated driving performance testing, if Occupational Therapy Driving Intervention (OT-DI) can improve the safe driving performance (less errors) over the short term (immediately following intervention) and intermediate term (3 months). Additionally, as a first step, we will discern the role of “battlemind driving” on driving errors and explore CV perspectives on safe driving pre and post war experiences as well as self-perceived successful rehabilitation strategies. We will meet this objective through the following specific aims: **Specific Aim 1.** Enhance the OT-DI with development of targeted simulator drives addressing CV driving triggers and assess user satisfaction (n=30). Significance - Simulator drives addressing newly identified triggers of CVs’ risky driving behavior will enhance the fidelity of simulator scenarios. The CVs for the evaluation phase 1 will not be drawn from the 260 CVs proposed for this study. **Specific Aim 2.** Evaluate group differences among the OT-DI group and the traffic safety education group measuring at baseline, post-intervention and three months post-intervention: (a) the type and number of driving errors made on a simulator, (b) CV and caregiver rating of driver difficulty, and (c) archival records, i.e. state-recorded violations, citations, and crashes. Significance - We will determine the impact of the OT-DI and traffic safety education on reducing driving errors, improving driving fitness, and potentially real-world outcomes of violations, citations, and crashes. **Specific Aim 3.** Determine effectiveness of the OT-DI, specifically addressing the impact of the OT-DI vs. traffic safety education in reduction of total driving errors and critical driving errors such as speeding measured during simulated driving. Significance - Critical errors made by CV such as speeding are understudied, and there is no published data to examine the effectiveness of a driving intervention for the CV population. **Specific Aim 4.** Examine the impact of the OT-DI and traffic safety education on real-world driving in a sub-set of CVs (n=30) using on-road testing. Significance - On-road testing provides the opportunity to compare CV’s simulated driving performance to performance in a more naturalistic environment. (The above CVs (n=30) relating to specific aim 4, will be selected from the 260 CVs proposed for the study.)

4. Background:

Overview of the literature: United States military engagements in Afghanistan, Operation Enduring Freedom (OEF), and Iraq, Operation Iraqi Freedom (OIF), have been fundamentally different from other wars. Particularly, the repeated exposure to explosions has increased Polytrauma, or blast explosions affecting multiple body systems or organs. As of this writing, over fifty thousand soldiers have been wounded in action and have sustained injuries affecting multiple body systems since the start of the wars [1]. Many of those are experiencing traumatic

brain injury (**TBI**), post-traumatic stress disorder (**PTSD**), as well as other **blast-related medical conditions** such as amputations, burns, chronic pain, visual or hearing loss [2]; all which threatens long-term safe driving upon return to civilian life.

It is estimated that 15% of OEF/OIF returnees sustained a mild TBI during deployment and that 19.1% from Iraq and 11.3% from Afghanistan meet criteria for PTSD [3]. PTSD rates are likely to increase in the next years as symptoms continue to emerge in the post exposure phase [4]. Specific TBI symptoms include blurred vision, headaches, dizziness, impaired concentration and memory, irritability, light sensitivity, motor coordination deficiencies, and nausea [5, 6] while PTSD symptom clusters are reliving the experience, hyperarousal, numbing, or avoidance [4]. TBI leads to debilitating cognitive, motor, and perceptual deficits, which can culminate in functional difficulties, such as unsafe operation of a motor vehicle. Often TBI co-occurs with PTSD, which further complicates driving safety due to concomitant road rage, (e.g. seeing other aggressive drivers as a personal and imminent threat), road panic (e.g. misinterpreting road debris as improvised explosive devices), and driving maneuvers inappropriate for non-combat conditions (e.g. not stopping for pedestrians). Returnees with other blast-related medical conditions (e.g. amputations, burns, chronic pain, visual or hearing loss) may experience limited range of motion and/or weakness, or an inability to safely operate a vehicle due to a missing limb or impaired body part. Another complicating factor is the persistence of wartime driving habits (driving in the middle of the road at high speeds, willingness to collide with oncoming traffic so as to protect the continuity of the convoy), termed as the “battlefield driving” mindset, after return to civilian life due to a lack of reintegration programs [7].

Driving is a portal into general life functioning and impaired driving skill can pose a serious threat to the CV, passengers and others; and involves increased risk of subsequent injuries, medical expenses and legal sequelae. In fact, **motor vehicle crashes (MVC)** among post deployed CV are one of the top four causes of injury and disability, hospitalization, and outpatient visits across the military, and are a *leading cause of death* among Army service members. [7]. In the young adult population, the top killers are unintentional injury, homicide, suicide, malignant neoplasms and heart disease [32]. The risk of MV death is significantly increased in years immediately following return from the battlefield. In sum, the effects of TBI/ PTSD/ other blast related injuries, combined with the “battlefield” mindset and lack of community reintegration programs place CV at risk for MVC and fatalities. ***The need for efficient assessments and interventions to reduce MVC post deployment has never been greater.*** A comprehensive driving evaluation, the gold standard, presents a risk for crash or adverse events in this population of CV. Alternately, simulated driving evaluation measures driving performance in a safe, accurate and objective manner [8] with evidence of absolute and relative validity when compared to real world (on-road) driving [9, 10]. Knowing who can or cannot safely resume driving, and providing rehabilitation for those with a potential for resuming safe driving could result in: increased safe driving behaviors (on simulator and on-road) [9, 10]; avoidance of injuries, collisions, citations and their residues; and resumption of safe driving with its attendant benefits in the realms of family functioning, participation in society and satisfaction with life.

Preliminary studies: Study 1: Institute for Mobility, Activity and Participation (I-MAP) and VA [11]. We used a STISM M500W fixed based driving simulator with 180° field of view to elucidate driving errors (number and type) within *18 returning combat Veterans (CV) with TBI/PTSD compared to 20 healthy adult civilian controls*. Participants with mild-moderate TBI were recruited from the North Florida/South Georgia Veterans Health System. Controls were

previously tested in a similar study [12] and all subjects were tested at UF's Driving Evaluation Center. **Results:** CV were younger, had a higher percentage of men, more racial diversity, less formal education, and lower cognitive scores than controls. Although the controls made more *signaling* errors ($t=19$, $p=0.046$, $SE=0.395$), CV made more critical driving errors such as *over speeding* ($t=4.095$, $p=0.001$, $SE=0.708$), *adjustment to stimuli* ($t=2.381$, $p=0.029$, $SE=0.140$), and a tendency for increased *gap acceptance* errors ($t=1.906$, $p=0.070$). These errors when made on the road may lead to crashes and/or injuries. Our findings provide early empirical support for developing safe driving interventions for CV to address the critical driving errors. **Study 2: I-MAP and VA** [33]: In analyzing the qualitative interviews conducted with the CV, preliminary findings ($N=5$) reveal that CV (1) drive defensively, as trained in the battlefield, upon return to civilian life; (2) can identify the triggers that elicit unsafe driving patterns; (3) are aware of their unsafe driving behaviors; and (4) require strategies to cope with these behaviors. **Study 3: I-MAP and VA** [14]: We conducted an evidenced-based review of assessment tools predicting on-road driving performance for persons with TBI. **Results:** Neuropsychological tests (2 Level II studies) are not predictive of on-road performance; *simulator (1 Level II study) and on-road (1 Level I study) studies may predict real world driving performance; Useful Field of View test of visual attention (4 Level II studies) predicts on-road driving in moderate to severe TBI; and self-report, other report, and post-injury disability status (1 Level II, 1 Level III, 1 Level IV) may be used as possible predictors of on-road performance.* This study provides empirical support to identify TBI specific evidence-based assessment tools in our driving battery. **Study 4: I-MAP and VA:** [15]. Using a STISM M500W fixed based driving simulator, we determined simulator sickness (SS) propensity [total SS score (TSS)] at baseline, after an initial 5-minute acclimation drive, and after an entire 20-minute drive within and between 21 CV with TBI/PTSD and 23 healthy controls (HC). **Results:** CV were younger and had a greater number of men; higher mean and maximum TSS scores at all three time periods; an increase in TSS between baseline and after the initial 5-minute acclimation drive in CV ($t=2.59$, $SE=8.10$, $p=0.02$) and HC ($t=2.51$, $SE=6.41$, $p=0.02$); and an increase in TSS between baseline and after the entire 20-minute drive in CV ($t=3.94$, $SE=8.06$, $p<.001$) and HC ($t=4.05$, $SE=4.10$, $p<.001$). A main effect of TSS approached significance ($F=2.78$, $p=0.057$, observed power = 62%) with CV scores higher than HC. Tukey's post-hoc test revealed that CV had higher mean TSS scores compare to HC at each time period. **Conclusions:** This is the first study to examine SS in CV with TBI/PTSD and provide early support that CV as a group have a greater propensity to, respond differently to, and experience a more severe reaction to stimuli evoking SS, as compared to an age cohort. **Study 5: I-MAP:** [16] We conducted an evidence-based review on simulator sickness. **Results:** Older clients (> 70 yrs), females, and mechanical/ engineering factors (e.g., refresh rates, scenario design and duration, simulator configuration and calibration) are *probably responsible* for increasing the rates of SS; while vection, speed of driving and postural instability *possibly* contribute to SS. **Study 6: I-MAP:** [12] We have instituted simulator sickness reduction strategies using I-MAP's standardized protocol. We have successfully reduced simulator sickness from 80 % to 25% among young and older adults. **Study 7: I-MAP and VA:** [34] This pilot study was our most recent effort funded by the DoD to examine the efficacy of an *Occupational Therapy Driving Intervention (OT-DI)* using clinical and simulated driving performance testing. Our main objective was to determine if the OT-DI, when compared to a traffic safety education intervention, can improve the safe driving performance (less errors) of CV. We tested the impacts of the OT-DI and traffic safety education over the short term (immediately following intervention) and intermediate term (3 months post). Specific Aims were: (1) Determine if driving errors (type and number) differ between the two groups (TBI/PTSD and orthopedic group) after baseline testing to discern the role of the "battlemind driving" phenomenon vs. medical diagnoses in unsafe driving behaviors.; (2) Examine the

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efficacy of the OT-DI with pre/post-testing, assessing driving performance on a DriveSafety CDS-250 simulator. CVs received three OT-DI sessions focusing on strategies to diminish driving errors and training in visual search techniques. (2a) Determine if the OT-DI, when compared to traffic safety education, is efficacious (decreases the type and number of driving errors on a simulator; improves caregiver responses on CV safe driving behaviors; reduces citations, violations or other driving mishaps in real world driving than controls) in the short term and over three months. (2b) Secondly, determine if community integration and satisfaction with life increase in the intervention group over the short and intermediate term. **Results:** Preliminary results have not been produced at this time for Specific Aim 1. For Specific Aim 2, a preliminary analysis was completed for CV (n=8) in the OT-DI arm only. Comparison to the traffic safety education group will not be analyzed until the completion of study testing, in order to maintain equipoise and study procedures for blinding. We used a Wilcoxon signed rank test to analyze differences in CVs' driving errors between baseline testing and post-test 1. The number as well as each type of DE made by eight CV (mean age= 39.38, $SD= 7.80$) was greater for baseline testing (mean= 31.63, $SD= 8.96$) compared to post-test 1 (mean= 15.38, $SD= 9.71$). At post-testing, the total number of errors, under speeding, and lane maintenance errors decreased the most. Although preliminary data suggests potential efficacy of the OT-DI, final testing compared to the control must still occur, as well as analysis three months after intervention. **Study 8: I-MAP and VA:** [36] We sought to examine the role of "battlemind driving" on driving errors and explores CVs' perspectives on safe driving pre and post deployment, and their self-perceived successful rehabilitation strategies using focus group methodology. **Results:** CVs reported using combat-related strategies during civilian driving, and discussed strategies they used to manage their driving environment. CVs described how environmental triggers such as road debris or loud noises led to flashbacks and subsequent aggressive driving. Overall, CVs reported that driving-related stress and driving difficulties impacted their everyday functioning. CVs employed a variety of environmental and vehicle control strategies to manage driving behaviors such as avoiding certain roads or locations and choosing to drive at low traffic times. CVs suggested future driving interventions include simulator-based scenarios and training that incorporates strategies for managing combat-related driving behaviors.

Previous experience of research team: Our prior work is strongly multi-disciplinary and leverages both unique and common resources and expertise at UF's I-MAP and the NF/SG VHS. At I-MAP, we have conducted pilot work examining the simulated driving performance issues of post-deployed OEF/OIF CV with TBI/PTSD (2008-2010); I-MAP has a driving evaluation battery with clinical tests empirically validated for predicting driving outcomes [17]; I-MAP has expertise employing driving simulation with TBI/PTSD [35]. and other medical conditions [12, 18]; and has conducted a qualitative study examining the personal experiences of CV assessed with a simulated driving test [33]; UF and the VA have an established track record of pilot work, publications and national presentations (see preliminary work) on TBI/PTSD and simulated driving performance of returning CV; I-MAP's current pilot utilizes a first of its' kind mobile simulator, facilitating testing of CV and intervention across the NF/SG VHS (see Intervention attachment for detailed description).



Figure 1.a. DriveSafety 250 Simulator



Figure 1.b. Dodge Caravan with lift.

5. Specific Aims:

The **overarching objective** of this proposal is to discern if an OT-DI is effective, i.e. does it improve fitness to drive abilities and result in reduced driving errors over the short term (post intervention) and intermediate term (3 months post), and impact real-world driving as measured by proxy report and (for a sub-group of participants) an assessment of on-road driving.

Specific Aim 1. Enhance the OT-DI with development of targeted simulator drives addressing CV driving triggers and assess user satisfaction.

1a. Develop two ten-minute drives with CV specific driving triggers. Obtain user evaluation (n=30) of these drives using a testing and review process and receive feedback including visual analog scale ratings comparing the new and existing drives. Scenario testing session 1 1b. Integrate the new drives into the existing intervention and conduct pilot testing with CV (Scenario testing session 2)..

These (n=30) participants will complete simulator testing of drives at two time points in phase 1 only and are not included in the randomized sample of combat veterans (n=260) due to confounding.

Rationale – The current scenarios are not capturing key triggers of CVs' risky driving behavior.

Significance - Simulator drives addressing newly identified triggers of CVs' risky driving behavior will enhance the fidelity of simulator scenarios.

Specific Aim 2. Evaluate group differences among the OT-DI group and the traffic safety education group measuring at baseline, post-intervention and three months post-intervention: (a) the type and number of driving errors (Table 3 below) made on a simulator, (b) CV and caregiver rating of driver difficulty, and (c) archival records, i.e. state-recorded violations, citations, and crashes.

2a. Compare OT-DI intervention group with traffic safety education group; assessing type and number of driving errors on a simulator and caregiver responses on Fitness-to-Drive Screening

Measure at baseline, immediately post-intervention, and three months post. 2b. Determine the long-range impacts of the OT-DI and the traffic safety education by analyzing the long-term data on real world outcomes of driving violations, citations, and crashes using state records.

Rationale – Combat Veterans need an evidence-based intervention to address their motor vehicle crash risk Significance - We will determine the impact of the OT-DI and traffic safety education on reducing driving errors, improving driving fitness, and potentially real-world outcomes of violations, citations, and crashes.

Specific Aim 3. Determine effectiveness of the OT-DI, specifically addressing the impact of the OT-DI vs. traffic safety education in reduction of total driving errors and critical driving errors such as speeding measured during simulated driving.

Rationale – The MVC rate for Veterans is attributed in part to these critical driving errors such as speeding. Significance - Critical errors made by CV such as speeding are understudied, and there is no published data to examine the effectiveness of a driving intervention for the CV population.

Specific Aim 4. Examine the impact of the OT-DI and traffic safety education on real-world driving in a sub-set of CVs (n=30) using on-road testing.

Rationale – We expect if improvement in simulated driving performance is seen, changes will also be present in real-world driving. Significance - On-road testing provides the opportunity to compare CV's simulated driving performance to performance in a more naturalistic environment.

6. Research Plan:

Study Design:

Phase 1: The study team will conduct a pilot testing and evaluation of the study drives by using 30 combat veterans. These participants will complete simulator testing of drives in two time points in phase 1 only and are not included in the randomized sample (N=260) due to confounding.

Phase 2: Using a repeated measures design, we will recruit and assess the driving performance of CV (N=260) focusing on those with potentially higher MVC crash risk from deployment experiences or medical conditions (mTBI, PTSD, or orthopedic). Following baseline testing, we will randomly assign CV to the OT-DI or traffic safety education group (each 3 sessions), followed by a post-test 1, and after 3 months, a post-test 2 (see Figure 2). We will also obtain caregiver or proxy (N=260) ratings of the CV's driving difficulty (baseline and post-test 2), along with measures of community integration, life satisfaction, and real world driving (violations, citations, and crashes from state reports).

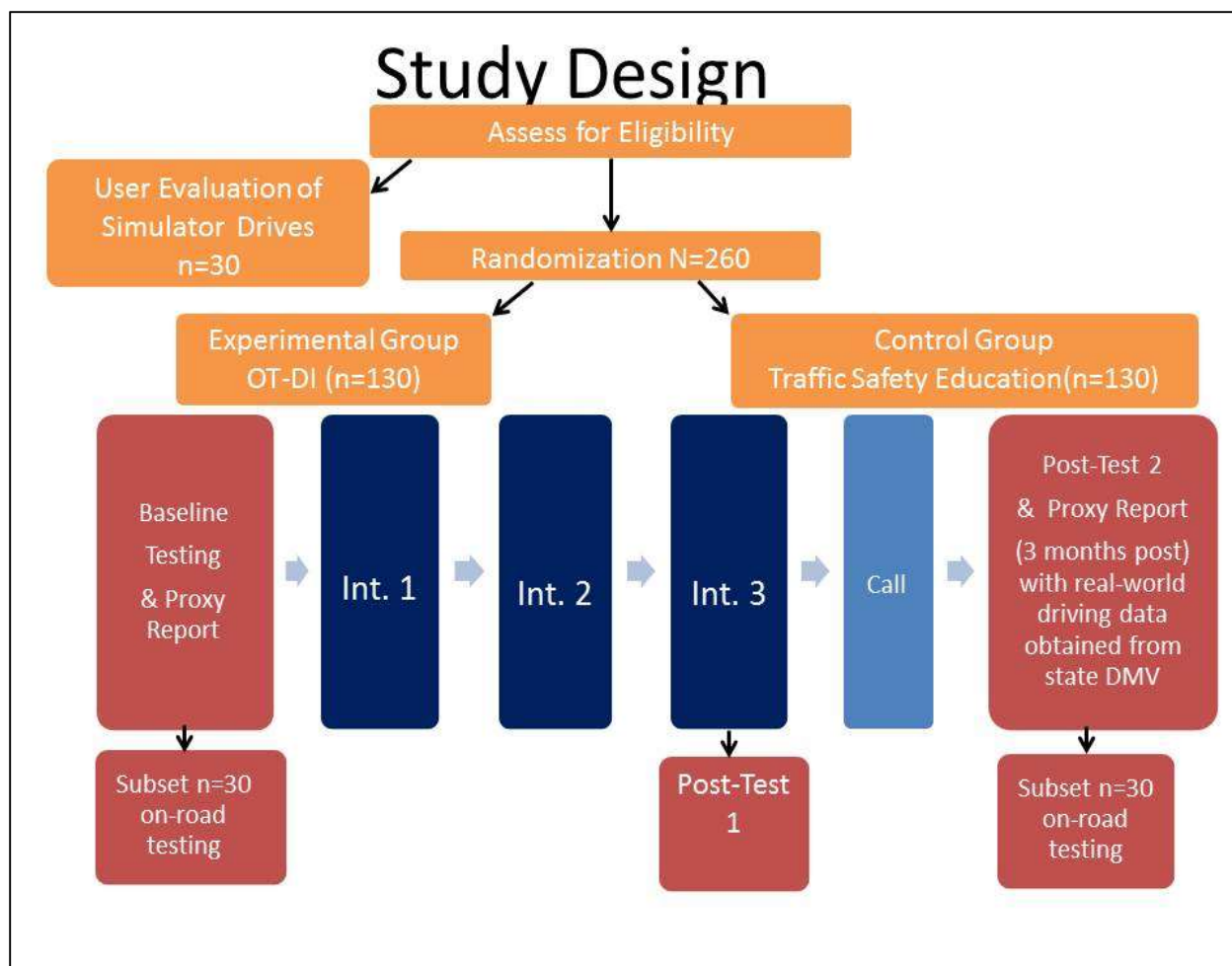


Figure 2. Overview of Study Design

Recruitment: CV will be recruited through the NF/SG VAMC's Physical Medicine and Rehabilitation Clinic, OEF/OIF & Seamless Transition Program, Women's Clinic, and Community-Based Out-Patient Clinics. Flyers will be distributed through VA clinical centers and community based veteran's organizations such as the Wounded Warriors' TRACK Program in Jacksonville, FL or Vet Centers. Additionally a briefing is going to be given at each of these sites by research personnel to inform clinicians and service providers (e.g. veteran service organization staff) of the study. Veterans will call a University of Florida study hotline for more information about the study and to ascertain eligibility.

Sample size: In this project, we are determining both the efficacy and the effectiveness of the OT-DI. We will recruit and test an additional 260 Veterans to determine if there are differences in the main dependent variable: *number of driving errors* (completing our pilot work on efficacy) and test the effectiveness of the OT-DI on reducing critical errors such as speeding. At the conclusion of the proposed study our total sample (pilot plus follow-on effort) of CV tested is estimated to be N= 300. Based on our pilot study data, ***to have the power of 80% to detect the differences for total driving errors and speeding between OT-DI group and traffic safety education group*** over the short term and intermediate term by controlling the overall Effectiveness of a Driving Intervention on Safe Community Mobility for Returning Combat Veterans

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type I error rate at 0.05, we would need total n=132 subjects. Assuming 40% attrition rate in this population across the study time period, an estimated n= 260 CV will be recruited and we anticipate 132 subjects will have completed the full protocol (baseline through 3 month post-test).

Inclusion criteria for Drivers: We will recruit and enroll CV both with diagnoses (TBI/PTSD, orthopedic injury and/or polytrauma) and CV without formal diagnoses who report driving issues (either formal such as violations, citations or MVC, or informal including risky driving or driving stress and/or anxiety). Included CV will have driven prior to their injury/condition; have a valid driver's license or are eligible for a driver's license; be community dwelling; have potential for following driving safety recommendations (MMSE 24/30); and be able to participate in a driving evaluation battery.

Exclusion criteria for Drivers: CV who have severe psychiatric (e.g., psychoses) or physical conditions (e.g., missing both arms and/or legs) that will limit ability to drive; have multiple psychotropic medications that may impact mental or physical (due to side-effects) functioning as per the consulting physician; have severe, un-remediable medical conditions (e.g., severe TBI) as per the consulting physician.

Inclusion/Exclusion for Caregivers: Inclusion criterion for caregivers is ability to complete a driving questionnaire pre and post intervention. Exclusion criterion is the presence of a cognitive or physical impairment that would hinder their ability to complete the questionnaires or make an active contribution.

Informed Consent Process:

Information about the study will be distributed through VAMC clinics and community locations as listed above. Interested veterans who call about the study will speak to a research staff member who will describe the study based on a script (see telephone script) and screen the subject for eligibility. Veterans who are eligible and want to enroll will be mailed a written informed consent and a HIPAA authorization form. Research staff will make a telephone appointment to review the consent and answer any questions. After the consent is reviewed by the potential subject, and consent is explained by research staff, the subject will be scheduled for baseline testing and a confirmation of this appointment mailed to the subject. At the first session and prior to any data collection the informed consent will be reviewed again, questions answered, and the consent will be signed by the participant and a trained research team member (research therapist). The staff member consenting has completed VA and University of Florida training on HIPAA and privacy issues. As per VA procedures a research note will be entered in the VA's electronic medical record (for those CV under VA care) indicating the CV's participation in the study and how to contact the PI regarding any medical or safety issues related to study participation.

Consent will take place at the discretion of the veteran or caregiver, and not during a time of mental or physical stress that would impact their decision to enroll. Subjects do not have to give an immediate response about enrolling and may freely discuss the study with people of their choice before making a decision. Capacity to consent will be decided by the consenting staff member in consultation with the PI and based on medical history and telephone screening. Caregivers will also receive an explanation of the study and their participation, and be able to discuss the study with a team member. They will complete a written informed consent at the baseline testing visit (if they are present) or by mail before participation.

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Compensation:

If a Combat Veteran (CV) or Caregiver is paid more than \$75 for taking part in this study, his or her name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. CVs and Caregivers are responsible for paying income taxes on any payments provided by the study. If the payments total \$600 or more or CV/Caregiver is a nonresident alien, payment will be processed through the University of Florida Accounts Payable department and the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: <http://privacy.ufl.edu/SSNPrivacy.html>.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

The study team will provide you with an informational form called the Prepaid Card Facts document. If you have any problems regarding your payment call the HSP Office (352) 392-9057.

Veterans will be reimbursed as follows:

Phase 1 – User evaluation of new simulator drives only

Session 1: Evaluation of drives = \$50

Session 2: Evaluation of integrated/revised drives = \$50

Phase 2 – Randomization to OT-DI or Traffic Safety Education

Session 1: Baseline testing = \$50.00

Session 2-3: Intervention or Traffic Safety Education = \$25.00 each

Session 4: Intervention or Education and Post-test 1= \$50.00

Session 5: Post-test 2 after three months = \$100.00

Caregivers will be reimbursed as follows:

For completing the Fitness-to-Drive Screening Measure (15 minutes) on the driver at baseline and after post-test 2 = \$25.00.

Caregivers: Payment will be a mailed check through the University Of Florida Department Of Occupational Therapy. Caregivers will receive payment approximately 6-8 weeks after completion of FTDS2.

Combat Veterans: CVs will receive payment in the form of gift cards after completion of each session.

Procedure: Using standardized protocol [16], *baseline testing—Pre-test 1*—will occur by administering I-MAP's clinical battery of tests [16] and a simulated driving test [16], , Community Integration Questionnaire [21], and a Satisfaction with Life Questionnaire [22]. Driving performance is measured in the simulator (see Intervention attachment for a detailed description). In addition to performance output measures generated by the simulator (e.g., lane position or speed), the OT-DRS evaluates the CV's driving and records the presence or

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absence of seven driving errors (Table 1) on a data collection form specific to each simulator drive. Caregivers/ family members will complete a proxy report to rate the CV driving behaviors using the Fitness-to-Drive Screening Measure (FTDS) (Classen, et al., 2010). After baseline testing, subjects will be randomly assigned to either the intervention group (OT-DI) or the control group (traffic safety education) both of which are detailed in the Intervention attachment. The intervention group receives Occupational Therapy Driving Intervention (OT-DI), which consists of three x 1 hour sessions (Session 1: Driving evaluator reviews explicit driving errors with CV; Session 2: Driving evaluator provide tailored strategies to mitigate errors; Session 3: CV drive simulator with targeted feedback from driving evaluator). *Fidelity* of these sessions are in accordance with the OT scope of practice and position paper for driving evaluation and rehabilitation (American Occupational Therapy Association [AOTA], 2010; AOTA, 2004). The control group will receive, according to a curriculum approved by the Florida Department of Highway Safety and Motor Vehicles, three sessions of traffic safety education (each approximately 90 minutes in length) which focus on person factors, vehicle factors, and environmental factors. These sessions are computer-based, interactive, and utilize a multifaceted approach to learning based on text, case examples, and video.

Equipoise (equality among two treatment arms and outcomes not known to the researcher), *blinding* (for baseline testing condition), and *intent to treat analyses* (concerted effort to mitigate attrition) will be maintained. Immediately after session 3 (same day, or as soon as can be scheduled), **Post-test 1** will occur using the same standardized protocol outlined for *baseline* testing. Participants will then be followed at the end of a three month period, only receiving a phone call to remind them of their last testing session — **Post-test 2**— and be tested again with the same standardized protocol as administered during *baseline* testing. Caregivers/ family members will rate the CV driving behaviors using the FTDS. At this time, we will also obtain real world driving data from the Department of Motor Vehicles (public records) for each CV including citations, violations, and recorded collisions / crashes. Regardless of the time period of driving data provided by the DMV (varies by state) we will analyze events that have occurred from date of participant's baseline session to 6 months post intervention (following post test2).

A sub-set of 30 drivers from the experimental and control groups will be selected to under-go on-road testing in a dual brake equipped vehicle in urban, residential and highway traffic conditions (gold-standard) at baseline and at the post-test 2, three months after intervention or education exposure. Drivers whose baseline testing indicates significant safety concerns (clinical test results or simulated driving errors indicating need for intervention and review by the medical monitor) will be excluded from on-road testing. This will be supervised by a Driving Rehabilitation Specialist (DRS), using on-road course materials established in prior research. [40] The University of Florida insures the vehicle and drivers in case of collision, although any citations or violations earned will be the responsibility of the driver.

Experiences from prior studies have showed us that computer and mechanical failures can occurs, thus the need to plan for make up sessions. In the case of mechanical or computer (simulator) malfunction, we will schedule a make up session to complete the testing. The make up session will be scheduled at the earliest convenience of the testing team; this session will be set within 2 weeks of the original testing date.

Table 1	Errors measured during simulated or on-road driving evaluation
Driving error	Definition
Vehicle Position	Vehicle position refers to the position of the vehicle forward and backward (anterior - posterior) in relation to other vehicles and/or objects and pavement

	markings. This captures following distance during forward movement and vehicle spacing during lane changes and merges. Examples of errors: Traveling too closely (tailgating), inadequate space cushion during merge or lane change, stopping across a crosswalk or too far back from either pavement markings or other vehicles.
Lane Maintenance	Refers to the lateral (side to side) positioning of the vehicle during driving maneuvers (turns, straight driving, lane changes, etc.) and reflects ability to maintain steering control. Examples of errors: Drifting out of driving lane, encroachments on perpendicular traffic or wide turns, parking outside designated space markings.
Speed	Reflects ability to follow and maintain speed limits and having adequate control of acceleration and braking features of the vehicle. Example of errors: not coming to a complete stop at stop sign, traveling too slow/fast, inadequate merging speed, abrupt or inappropriate braking or acceleration.
Yielding	Giving right-of-way when appropriate. Yielding refers to the ability to recognize common rules of road safety. Yielding is assessed at four-way or two-way stop intersections (when other vehicles are present), right turns on red, and merges.
Signaling	Proper use of turn signals. Errors in signal use consist of leaving the turn signal on, not using the turn signal when turning, using the turn signal inappropriately (wrong signal for given turn, signaling too short until maneuver).
Visual Scanning	Demonstrating visual scanning of driving environment. Examples of errors: Not checking blind spot, not looking through rearview or side mirrors during lane changes, not looking left/right before proceeding through intersection. Eye check mirrors help determine proper scanning.
Adjustment to Stimuli/Traffic Signs	Ability to appropriately respond to driving situations. This captures ability to adjust appropriately to changing road sign information, other vehicle movements, pedestrian movements and ability to recognize potential hazards. Errors would consist of not adjusting speed for posted limits, not following proper directions given by evaluator, choosing improper lane from posted signage, improper response to traffic or pedestrian (or cyclist) movement.

Data collection and management: All data will be collected by a trained research assistant and data will be entered into password protected and secure server network consistent with the security, privacy and confidentiality policies of UF and the VA. Data collection will occur as follows: Baseline testing (health and driving questionnaires, all clinical tests and simulated driving evaluation), three sessions of simulated driving training or traffic Safety education, Post-test 1 (repeat of tests and measures from baseline), post-test 2 (repeat of tests and measures from baseline, and obtain driving record from Department of Motor Vehicles). Caregivers will be asked to complete a FTDS at baseline and again during the post-test 2 period.

Simulated driving evaluation and driving training will occur in the DriveSafety 250 mobile simulator (as described above) and the VA's Simulator located at the Smart house-Oak Hammock. In addition to simulator outputs measuring variables such as speed and lane maintenance, the driving specialist will record observations for up to three drives (forms included for (1) rural/suburban, (2) town/country and (3) city/ highway).

Clinical tests utilized include: I-MAP's clinical battery of tests including:

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- Health and driving questionnaires
- Medications Audit
- Fitness-to-Drive Screening Measure
- Clinical Driving Assessment (includes Optec vision screening, Useful Field of View, Range of Motion, Strength,)
- Propensity for Angry Driving Scale (Road rage questionnaire)
- Community Integration Questionnaire
- Satisfaction with Life Questionnaire

These forms are listed on Addendum S and psychological measures form and included with this submission.

Analysis:

Phase One: For analysis of the simulator drives we will use a questionnaire with visual analog scaling to rate the new drives compared to the prior versions to ascertain improvement and user satisfaction.

Phase Two: The overall objective of the study is to examine if an Occupational Therapy Driving Intervention (OT-DI) is more effective, i.e. does it improve safe driving performance (less errors) over the short term (post intervention) and intermediate term (3 months post), than the traditional traffic safety education program does. In the data analysis for this study, we shall first conduct a descriptive analysis to obtain baseline characteristics distributions about the subjects recruited and randomized to different treatment groups. In the subsequent statistical analysis, the mixed effects model [37] will be used to model the repeated measurement data and the covariance structures among the repeated measurements. The optimal model deemed for the data will be determined via the model selection strategy [38] among a set of candidate mixed effects models. The candidate mixed effects models include the treatment assignment, time, and time by treatment interactions in along with different commonly used covariance structures such as compound symmetry, autoregressive, and unstructured, etc. In case of high missing rate, we shall examine the baseline variables carefully and include the imbalanced baseline covariates in the mixed effects model to reduce the bias of parameter estimates due to the confounding issues resulting from the missing data.

As exploratory analysis, we shall conduct parametric test (e.g. t-test) and/or nonparametric tests (e.g. Wilcoxon and permutation test) on other exploratory outcome variables such as on-road testing errors, community integration, satisfaction with life, violations, citations, crashes and other driving errors (i.e. lane maintenance, speeding, visual scanning, gap acceptance, and adjustment to stimuli).

Labeling and storage of data & specimens: Per VA policy, all study documents (i.e. hard copies of clinical test forms, data collection forms, and consents) will permanently be stored at VA's CINDRR officer in a locked secured office designated by VA's Administrative Officer. . De-identified hard copy records for this study will be temporarily maintained at UF's College of Public Health and Health Professions while the subjects are active, and files maintained in the VA's CINDRR for long-term storage. All de-identified electronic data related to this study during the analysis phase of the study will be stored on secure networks at the UF College of Public Health and Health Professions and VA's CINDRR and maintained according to VA and UF policies. This study has no specimens.

Confidentiality: Accurate and complete study records will be maintained and made available to representatives of the U.S. Army Medical Research and Materiel Command. These

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representatives are authorized to review research records as part of their responsibility to protect human research volunteers. Research records will be stored in a confidential manner so as to protect the confidentiality of subject information

Review of research records: Accurate and complete study records will be maintained and made available to representatives of the U.S. Army Medical Research and Materiel Command. These representatives are authorized to review research records as part of their responsibility to protect human research volunteers. Research records will be stored in a confidential manner so as to protect the confidentiality of subject information.

Reporting of adverse events and unanticipated problems: Reporting of all unanticipated problems involving risk to subjects or others, or serious adverse events will be reported to the UF IRB-01 and the VA RORC Research Office. In addition, all unanticipated problems involving risk to subjects or others, serious adverse events related to participation in the study and subject deaths related to participation in the study will be promptly reported by phone (301-619-2165), by email (hsrrb@det.amedd.army.mil), or by facsimile (301-619-7803) to the USAMRMC, Office of Research Protections, Human Research Protection Office. A complete written report will follow the initial notification. In addition to the methods above, the complete report will be sent to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-ZB-PH, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

Barriers and solutions: Table 4 outlines the problems we anticipate to encounter in the conduct of this study and our solutions. Through our pilot work, and the associated challenges, we responded by creating strategies and infrastructure to administer a successful study and thus are prepared to move forward with this follow-on effort.

7. Possible Discomforts and Risks:

1. For some participants this study involves a driving evaluation including an on-road test. Our previous studies where we conducted on-road driving test, our experience show that there is a low risk likelihood of vehicle crash occurring (3 minor crashes in 14year period, which were Property Damage only and no injuries).

However, if the driving evaluator identifies significant safety concerns during the on-road test (such as lack of attention to driving or insufficient ability to see or react while driving), the driving evaluator will report these concerns to the study's medical monitor (VA physician). At the discretion of the medical monitor the participant will be referred for additional care within the VA system. Should the medical monitor judge that an on-road evaluation of driving is needed this will be conducted by the research therapist. In the event that a participant is determined to be unsafe to drive following the on-road evaluation, the DRS will inform the medical monitor who may choose to report the participant to the Department of Highway Safety and Motor Vehicles for review by the medical board whose actions may include license revocation.

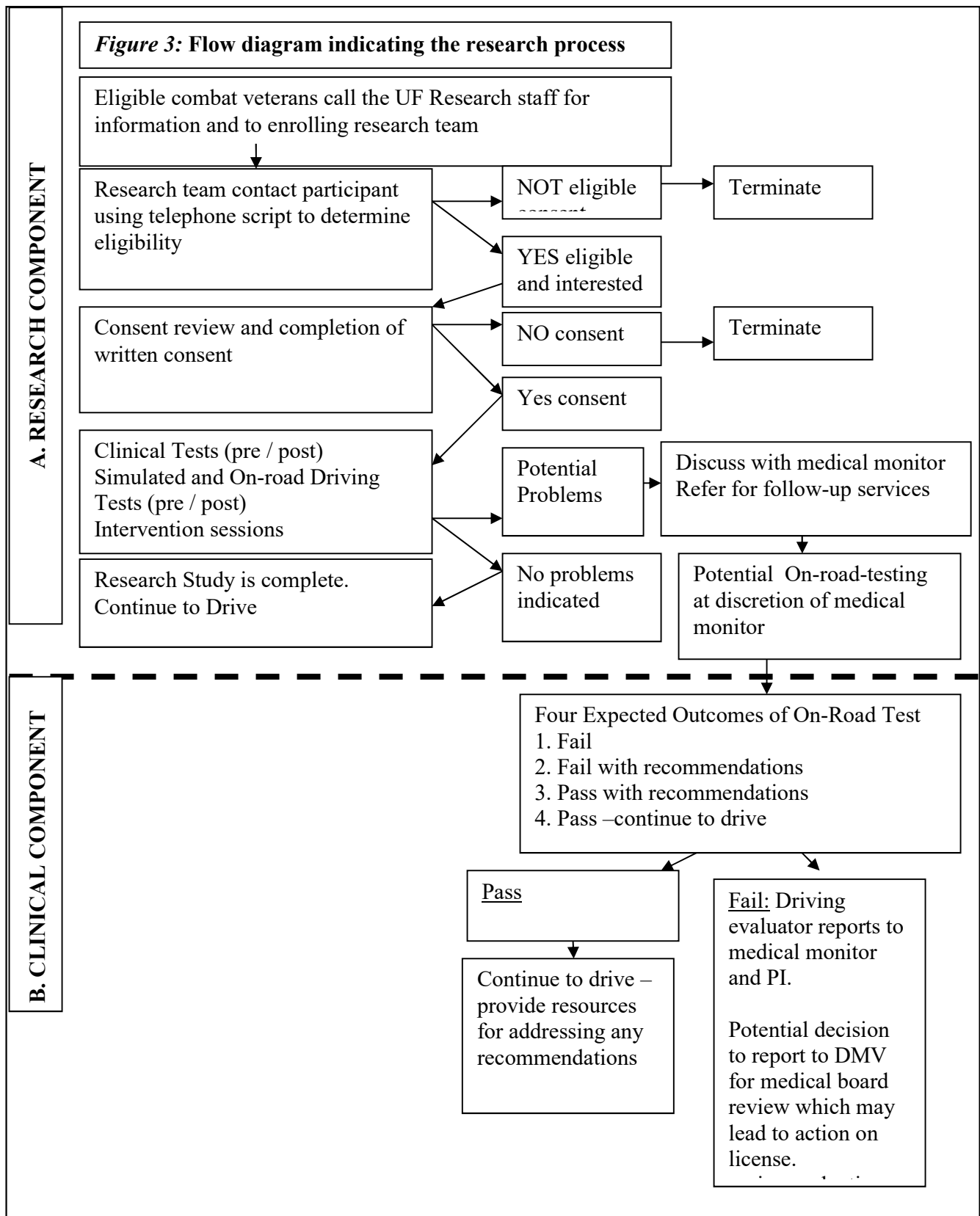
While the participant has the option to refuse the on-road driving evaluation, the driving rehabilitation specialist is still ethically bound to discuss her concerns with the VA medical monitor and possibly report the driver to the Department of Highway Safety and Motor Vehicles (See the Flow diagram in Table 3) for assessing them keeping their drivers licenses, under each of the following conditions:

- If no improvements in driving errors are made after driving rehabilitation
- If they prove to be unsafe drivers as determined by the Driving Rehabilitation Specialist

- If they continue to put themselves and other road users at risk for crashes, injuries or fatalities as determined by the Driving Rehabilitation Specialist.
2. As part of this study we ask about unsafe driving behaviors. Some of the questions we ask may be sensitive, and create psychological discomfort. Subjects are able to skip questions they do not wish to answer.
3. Caregivers will be asked to fill out a Fitness-to-Drive Screening Measure (FTDS) concerning the CV they are related to, friends with or caregivers of. As part of filling out the questionnaire, they will be asked to answer questions that may make them feel uncomfortable. They have the choice to not answer a question or questions and/or stop filling out the questionnaire at any time.
4. Participants driving the simulator may be prone to developing and experiencing simulator sickness. In the current study, we are taking many measures to reduce the occurrence of simulator sickness. These measures include:
- Increasing the correspondence between the various sensory cues:
 - We are making a concerted effort to provide compatibility between the various simulator subsystems in order to reduce incompatible sensory signals that bring about simulator sickness. In the design of our driving simulator we provide appropriate auditory and “seat-of-pants” motion cues, which are coordinated with the high fidelity visual display.
 - Communications with researchers who use similar systems allow us to employ their experience in coordinating and calibrating our simulator’s subsystems.
 - Utilizing an acclimation protocol:
 - An acclimation period of approximately 15 minutes will be given before the experiment begins. During the acclimation period, participants will begin with simple and slow straight line driving without much texture in the road image. Then, speed, texture, curves and turns will be progressively added.
 - During and after the acclimation period participants will be carefully observed and asked for verbal feedback regarding the presence of motion sickness.
 - Employing motion sickness questionnaires:
 - Participants will be screened before driving the simulator by asking questions about their susceptibility to motion sickness.
 - Those who show likelihood to exhibit simulator sickness symptoms will be notified and encouraged to use mitigation strategies such as light snacking before simulator use, cool air-conditioned testing space, water or soft drinks (e.g. gingerale), and frequent breaks. .
 - Participants will complete a questionnaire about the extent of their motion-sickness symptoms after completing the simulator-driving task to ensure that they are symptom free before leaving the premises.
 - Determining the extent of symptoms:
 - Participants will be observed and asked for verbal feedback throughout the actual simulation experiment as well.
 - If at any point throughout the experiment the participant reports, or is observed to have simulator sickness, the trial will be terminated. The participant will then be given the opportunity to proceed or to quit further simulator trials. Subjects

who do not tolerate simulation can be withdrawn from further participation by the study PI or medical monitor.

- Supplying environmental controls (the following have been compiled from personal communications with researchers and clinicians who suggested that these measures may be helpful in diminishing simulator-sickness symptoms)
 - The Dodge Sprinter van, where the simulator is housed, will be kept cool (under 75⁰) and a fan will be directed at the “driver”.
 - The total time of driving simulation will not exceed 30 continuous minutes of “driving”.
 - “Sick bags” will be available to participants in the simulator.
- If participants experience symptoms after driving we will measure motion sickness with the Simulator Sickness Questionnaire. We will allow a recovery period for the participants and monitor them for 10-minute intervals up to 30 minutes, to determine if the motion sickness symptoms have dissipated. If not, after 30 minutes, we will arrange for the participant to be transported to their home or a location of their choice. If symptoms are severe (rare occurrence) we will arrange for medical care. Any adverse events will be reported to the PI, the medical monitor, the IRB, as well as to the VA and the DOD OHRP. In case of injury, the Driving Rehabilitation Specialist, assisted by the doctoral level research assistant will call 911, then a family member, caregiver or significant other. Subsequently, the study PI and medical monitor will be contacted.



8. Possible Benefits:

There is potential for direct benefit to some participants, veterans who will receive counseling on driving behaviors. This project makes an original and important contribution to the goal of advancing research on the detection of safe driving ability of the CV with TBI/PTSD and orthopedic conditions and understanding the personal experiences underlying their unsafe driving habits. We will examine the efficacy of an OT-driving intervention and if successful we may prevent driving mishaps (MVC and other adverse effects) in the community and facilitate safe driving; produce a valid and reliable way of using the simulator to assess driving performance in this CV population; reveal intervention strategies that can be used to enhance real world driving; produce evidence for driving rehabilitation clinical practice; and enhance community integration, familial life, and satisfaction with life. Most importantly, we will provide strategies for mitigating the number one killer of post-deployed CV which is motor vehicle fatalities.

9. Conflict of Interest:

No conflict of interest exists as it relates to any of the investigators and this protocol, beyond the professional benefit from academic publication or presentation/dissemination of the results of this study.

10. References:

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Appendices:

Participant Forms

Study flyer

Informed Consent Form

Authorization for Release of Protected Health Information for Research Purposes

Data Collection forms / measures:

A. Measures to be conducted in telephone interview:

Driving Behavior Interview

Community Integration Questionnaire (CIQ)

Satisfaction with Life Scale (SWLS)

Health related information – telephone interview

SF-36 version 2 overall health

Simulator Sickness Questionnaire

B. Measures to be conducted during in-person sessions

Any measures from “A” that were not completed in telephone interview due to time considerations, or preference of the participant

Independence Drive Clinical Assessment form

Symbol Digit Modalities Test

Letter Cancellation

Rules of the Road and Signs Test

Medications Audit

Simulator Data Collection forms for 3 Drives (Residential/Suburban, Town/Country and City/highway)

Propensity for Angry Driving Scale (Road rage questionnaire)

C. Caregiver only

Fitness-to-Drive Screening Measure

IRB/ VA Forms

Introductory Questionnaire

Medical Center Support Form (with attached abstract and budget)

Scope of Practice, Conflict of Interest, and training records for team members

Study Registration and Initiation Checklist for Research and Compliance

Principal Investigator Request for Waiver of HIPAA Privacy Authorization for Research

Addendums A, S, V

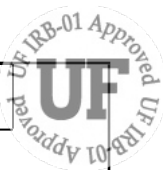
Psychological Measures Form

Serious and Unexpected Adverse Event & Safety Report Form



Department of Veterans Affairs

VA RESEARCH CONSENT FORM



Subject Name: _____ Date _____

Title of Study: Effectiveness of a Driving Intervention on Safe Community Mobility for Returning
Combat Veterans

Principal Investigator: Sherrilene Classen, PhD

VAMC: North Florida/South Georgia
Veterans Health System
UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM

to Participate in Research
INTRODUCTION

Name of person seeking your consent: _____

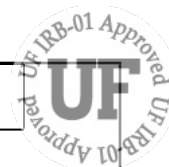
Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will also describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any VA or other benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, concerns, complaints, wish to discuss problems or talk to someone independent of the research staff, obtain information, or offer input, please call either of the following offices: (1) the University of Florida Institutional Review Board (IRB) office at (352) 273-9600; or (2) the North Florida/South Georgia Veteran's Health System Research Service Office at (352) 548-6069.



Department of Veterans Affairs

VA RESEARCH CONSENT FORM



Subject Name: _____ Date _____

 Title of Study: Effectiveness of a Driving Intervention on Safe Community Mobility for Returning
 Combat Veterans

Principal Investigator: Sherrilene Classen, PhD

 VAMC: North Florida/South Georgia
 Veterans Health System

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

For PI Use:

Participant Social Security Number: _____

SSN should be written on this consent form by the research team prior to scanning into the VHA health record; if the subject does not have a VHA health record, this requirement is N/A.

2. What is the Title of this research study?

 Effectiveness of a Driving Intervention on Safe Community Mobility for Returning
 Combat Veterans

3. Who can you call if you have questions concerns, or complaints about this research study?

Principal Investigator: Sherrilene Classen, PhD; 352-273-6883

Other research staff: 352-273-6024

4. Who is paying for this research study?

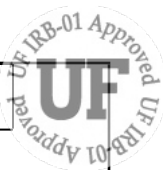
The sponsor of this study is Department of Defense

 Funding Agency: Department of Defense – U.S. Army Medical Research and Material
 Command - Telemedicine and Advanced Technology Research Center



Department of Veterans Affairs

VA RESEARCH CONSENT FORM



Subject Name: _____ Date _____
 Effectiveness of a Driving Intervention on Safe Community Mobility for Returning
 Title of Study: Combat Veterans
 Principal Investigator: Sherrilene Classen, PhD VAMC: North Florida/South Georgia
 Veterans Health System

5. Why is this research study being done?

The purpose of this research study is to see if driving evaluation, driving training or education including ways to get around in the community help improve safety for combat veterans. We want to help combat veterans living with disabilities to be able to continue to drive safely as long as possible using driving testing, training, and education. For veterans who do not drive or can no longer drive, education on other ways to get around in their community can help them stay active and get to places outside their home such as a store or the doctor's office. Inability to drive or loss of independence in community mobility may lead to depression, social isolation, or reduced health.

This project will address the community mobility needs of veterans including those living in rural areas that lack healthcare services. With our focus on independent and safe driving and independence in community mobility the study goals are:

- (1) Enhancing an occupational therapy driving intervention for returning combat veterans through the development of tailored simulator drives incorporating driving challenges and trigger events.
- (2) Testing the simulator based driving intervention in comparison to an educational intervention. We want to know how the interventions work to reduce driving errors and impact citations, violations or other driving mishaps in the real world.
- (3) Determining if the interventions have an impact on the driver's community activity and satisfaction with life.

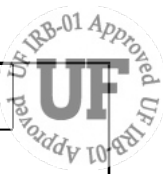
You are being asked to be in this research study because you are a combat veteran who has reported difficulty with some aspect of driving and an interest in helping us test simulator drives by sharing your experience and feedback.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.



Department of Veterans Affairs

VA RESEARCH CONSENT FORM



Subject Name: _____ Date _____
 Effectiveness of a Driving Intervention on Safe Community Mobility for Returning
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 Veterans Health System

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

We are evaluating new drives for the simulator and there is no normal clinical care. Combat veterans will use the visual analogue scale to rate the new drives.

7. What will be done only because you are in this research study?

Before the testing sessions you will be called by study staff to see if you can be included in the study. After we know you are eligible and interested in the study, a written consent will be mailed to you and then reviewed during a phone appointment. We will ask you about days and times that will work for the initial testing session and set a time to go over the consent.

We will look at how you drive a driving simulator. The simulator is mounted in the cargo section of a Dodge Sprinter van. Testing sessions for this portion of the study will occur at safe and secure community locations such as a community VA location or UF smart house at Oak Hammock.

Prior to any testing, you will go through tasks on the simulator to get used to it (15-30 minutes). As you get used to the simulator, driving will be on simple and slow roads. Then speed, road texture, curves and turns will be added to the scene as you drive. The driving simulation takes up to 1 hour to complete. Participants in this phase of the study will have two sessions of testing newly developed simulator drives.

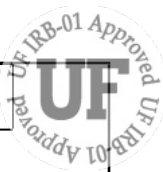
As you use the simulator we will watch you and ask you how you feel. This is because some people get uncomfortable when they drive a simulator. See #10 below for more details.

The Principal Investigator listed in question 3 of this form and the research team conducting the research procedures described above will monitor how you do during the research. If you have any questions about the research procedures now or at any time during the study, please contact one of the research team members listed in question 3 of this form.



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Subject Name: _____ Date _____

Title of Study: Effectiveness of a Driving Intervention on Safe Community Mobility for Returning
Combat Veterans

Principal Investigator: Sherrilene Classen, PhD

VAMC: North Florida/South Georgia
Veterans Health System**8. How long will you be in this research study?**

To start, there is a 30 minute phone call with questions about your eligibility for the study as well as information on the informed consent forms. There will be two driving sessions, both will take one to two hours. In the case of mechanical or computer breakdown, we will schedule a make-up session to complete the testing. The make-up session will be scheduled at the earliest convenience of the testing team; this session will be set within 2 weeks of the original testing date.

9. How many people are expected to take part in this research study?

Up to 30 combat veterans from North Florida and South Georgia are expected to participate in the testing phase (phase 1) of the study. An additional 260 combat veterans and 260 caregivers will participate in the intervention phase (phase 2) of the study.

**WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND
WHAT ARE YOUR OPTIONS?**
10. What are the possible discomforts and risks from taking part in this research study?

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability. Question 17 in this form discusses what information about you will be collected, used, protected, and shared. This study also uses a HIPAA form to give you more details on how we use your information.

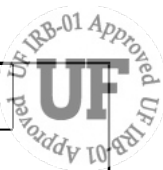
Possible risks to you may include: Some people driving the simulator may feel symptoms like motion sickness. In this study we are taking steps to lessen the chance of simulator sickness including:

1. Driving the simulator was created to feel as close to life-like as possible. This helps reduce sickness.



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 Veterans Health System

2. We give you tasks so you get used to what it feels like to drive the simulator and slowly increase speed, road texture, curves and turns.
3. We watch you drive and ask you about how you feel, before, during and after any driving to check for simulator sickness. If you are more likely to feel sick, we will tell you and offer ways to reduce your risk. If at any point you tell us, or we can see that you don't feel well, your driving will be stopped. After a break and use of strategies such as cool air or ginger ale, we will discuss with you whether or not another attempt should be made at simulated driving. It is always your choice to stop driving or to withdraw from the study if simulated driving makes you uncomfortable.
4. We will ask you again how you feel after you are done driving to make sure that you are well enough to go back to activities before we end the session.
5. Set up of van to prevent/reduce sickness.
 - The Dodge Sprinter van will be kept cool (under 75°) and a fan will be directed at the "driver".
 - Each driving task will not be more than 30 minutes.
 - "Sick bags" will be on hand for use as needed.
6. If you feel sick after driving we will give you time to recover and will check how you feel every 10 minutes for up to 30 minutes, to see if you are feeling better. If you are not feeling better we will talk with you about options such as medical care or assistance with a ride home.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this consent form or the person reviewing this consent with you before enrolling in this or any other research study or project.

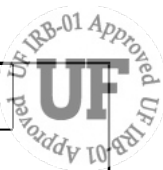
Throughout the study, the researchers will notify you of any new information that may become available and might affect your decision to remain in this study. This includes, but is not limited to, information that may affect your safety, well-being or medical care.

If you wish to discuss the risks or discomforts described above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 of this form.



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Subject Name: _____ Date _____

Title of Study: Effectiveness of a Driving Intervention on Safe Community Mobility for Returning
Combat Veterans

Principal Investigator: Sherrilene Classen, PhD

VAMC: North Florida/South Georgia
Veterans Health System**11a. What are the potential benefits to you for taking part in this research study?**

We do not expect benefits to participants in this phase of the study.

11b. How could others possibly benefit from this study?

The user testing of new simulator drives will help us refine our intervention to meet the needs of returning combat veterans. In addition, we will learn about the driving performance, community activity, and life satisfaction of combat veterans who report driving difficulty post-deployment. We also learn about the impact of medical conditions common in veterans from conflicts in Iraq and Afghanistan such as Traumatic Brain Injury (mTBI), Post Traumatic Stress Disorder (PTSD) or Orthopedic injuries. Others will benefit if this information is used to help create driving programs for returning veterans and to improve driving evaluations.

The results of this study could also help physicians better identify which of their patients may be unsafe to drive. Some of these patients may be able to drive safely after the physician refers them to others for treatment (an eye doctor, for example) while those patients who are not safe to drive will be advised to stop. Removing dangerous drivers from our roads may make driving safer for everyone.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

The option to taking part in this study is doing nothing. If you do not want to take part in this study, tell the Principal Investigator and do not sign this Informed Consent Form.

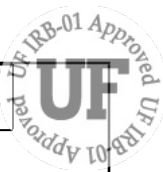
13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.



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If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected will continue to be used to the extent that the researchers have used it in this research study.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

1. You did not qualify to be in the study because you do not meet the study requirements.
2. If you did not follow the instructions given to you by the research study staff or investigators.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

No.

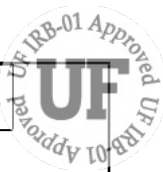
The Sponsor will only pay for medical services that you receive as part of your participation in this study as described in question 7 above.

There will be no costs to you for any procedure, treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not being done only for this study (e.g., normal hospital and prescription expenses which are not part of the research study) will be charged to you or your insurance. These costs may not be charged if you are a veteran and you are being treated at the North Florida/South Georgia Veterans Health System (NF/SG VHS), however some Veterans are required to pay co-payments for medical care and



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 Veterans Health System

services provided by the VA. These co-payment requirements will continue to apply to VA-provided medical care and services that are not part of this study."

15. Will you be paid for taking part in this study?

Yes, you will be paid for participating in this research study through the University of Florida College of Public Health and Health Professions. You will be paid \$50 for each for the evaluation of drives and the evaluation of the integrated/revised drives. We will process payment for each session after it occurs. Payment will be given in the form of gift cards. If you withdraw or do not participate in all parts of the study, you will be paid only for the parts that you completed.

If you are paid more than \$75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to **nonresident aliens** must be processed through the University of Florida Payroll and Tax Services department. If the payments total \$600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: <http://privacy.ufl.edu/SSNPrivacy.html>.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study coordinator.

16. What if you are injured because of the study?

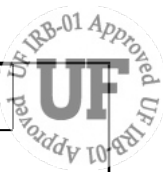
Please contact the Principal Investigator listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

If you experience an injury or illness as a result of your participation in this VA approved research study, all medical treatment considered necessary by your



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Combat Veterans

Principal Investigator: Sherrilene Classen, PhD

VAMC: North Florida/South Georgia
Veterans Health System

physician (emergency as well as medical treatment beyond emergency) will be provided by the VA. There will be no cost to you, unless you fail to follow the directions of the study procedures. Care will be provided at a VA medical facility unless the VA medical facility is not capable of providing the care. If this occurs, you will be treated by a private facility or physician and the VA will pay the private facility or physician for the reasonable cost of your care. In some cases the VA may approve private care for a non-veteran.

If you do not follow study procedures, you may be treated by the VA on the basis of your veteran's eligibility. If you are not a veteran and have not followed study procedures the VA can only provide limited care at your expense. No additional money has been set aside for pain, suffering or any money losses you may suffer during your treatment. You have not waived any legal rights by signing this form.

In the event of a research-related injury, have questions about any discomforts that you experience while participating in this study or if you experience an adverse reaction, please immediately contact the Principal Investigator listed in question 3 of this form during the day on 352-273-6883 and after business hours on 352-221-3041. If you seek emergency hospitalization in a private hospital because you are unable to come to the VA, have a family or friend contact your study doctor so that the VA can coordinate care with the private hospital.

17. How will your privacy and the confidentiality of your research records be protected?

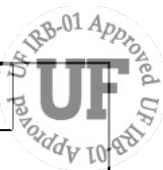
This is a collaborative study between the University of Florida (UF) and Veterans Affairs (VA). All VA data and records will be stored at the VA in a locked research office. Only de-identified data will be analyzed at the University of Florida. All de-identified hard copies (paper records) will be stored temporarily at UF during the study sessions and will be transferred to the VA for long-term storage. The final dataset will be stored on a protected server at the VA.

Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking



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Veterans Health System

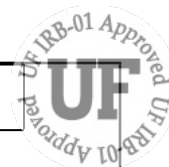
part in research). Certain federal agencies such as the Office for Human Research Protections (OHRP), representatives of Department of Defense, the VA Office of Research Oversight (ORO), or the VA Office of the Inspector General (OIG) that oversee human subject research may also have the legal right to review your records. Otherwise your research records will not be released without your permission unless required by law or a court order.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability. If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.



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Subject Name: _____ Date _____

Title of Study: Effectiveness of a Driving Intervention on Safe Community Mobility for Returning
Combat Veterans

Principal Investigator: Sherrilene Classen, PhD

VAMC: North Florida/South Georgia
Veterans Health System**SIGNATURES**

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how privacy will be protected:

Signature of Person Obtaining Consent_____
Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your privacy will be protected. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

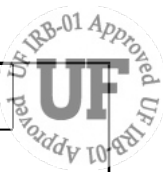
You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting_____
Date



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Subject Name: _____ Date _____

Effectiveness of a Driving Intervention on Safe Community Mobility for Returning

Title of Study: Combat Veterans

Principal Investigator: Sherrilene Classen, PhD

VAMC: North Florida/South Georgia
Veterans Health System
INFORMED CONSENT FORM
to Participate in Research
INTRODUCTION

Name of person seeking your consent: _____

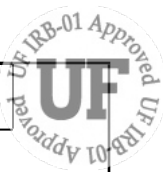
Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will also describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any VA or other benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, concerns, complaints, wish to discuss problems or talk to someone independent of the research staff, obtain information, or offer input, please call either of the following offices: (1) the University of Florida Institutional Review Board (IRB) office at (352) 273-9600; or (2) the North Florida/South Georgia Veteran's Health System Research Service Office at (352) 548-6069.



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Subject Name: _____ Date _____
 Effectiveness of a Driving Intervention on Safe Community Mobility for Returning
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 Veterans Health System

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

For PI Use:

Participant Social Security Number: _____

SSN should be written on this consent form by the research team prior to scanning into the VHA health record; if the subject does not have a VHA health record, this requirement is N/A.

2. What is the Title of this research study?

Effectiveness of a Driving Intervention on Safe Community Mobility for Returning
 Combat Veterans

3. Who can you call if you have questions, concerns, or complaints about this research study?

Principal Investigator: Sherrilene Classen, PhD, (352) 273-6883

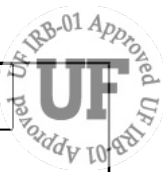
For emergencies, after hours or on weekends or holidays: Sandra Winter 352-214-3436. If you happen to not be able to reach any of the above, please leave a message at one of the numbers and someone will call you as soon as possible.

Other research staff: TBD, 352-273-6024

4. Who is paying for this research study?

The sponsor of this study is Department of Defense

Funding Agency: Dept of Defense – U.S. Army Medical Research and Material
 Command - Telemedicine and Advanced Technology Research Center



Subject Name: _____ Date _____
 Effectiveness of a Driving Intervention on Safe Community Mobility for Returning
 Title of Study: Combat Veterans
 Principal Investigator: Sherrilene Classen, PhD VAMC: North Florida/South Georgia Veterans Health System

5. Why is this research study being done?

The purpose of this research study is to study driving evaluation and to look at two methods of driving training in certain combat veterans (CV). As part of the study, we are using the Fitness-to-Drive Screening Measure (FTDS) to get information about the driving behaviors of combat veterans. It is a paper and pencil questionnaire about driving habits and driving difficulty.

You are being asked to be in this research study because you are a caregiver, friend or family member of a combat veteran who has identified you as a person that can answer questions about his or her driving habits.

The information we get from you from the FTDS will be used as one part of all the information we collect for the study. You will complete the questionnaire at two different times for this study.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

Normal clinical care is medical or other treatment or services that you would receive even if you did not participate in this research study.

We are studying two ways of driving skills intervention for combat veterans and there is no normal clinical care for caregivers.

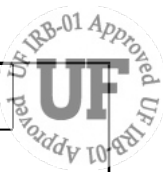
7. What will be done only because you are in this research study?

A combat veteran you know will ask you to be in the study to answer some questions about his or her driving. You will be given the phone number to contact study staff who will tell you about the study. If you agree you will complete a written consent. We are asking you to complete the Fitness-to-Drive Screening Measure (FTDS) two times over the course of the study. We will give you the FTDS at the combat



Department of Veterans Affairs

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veteran's first testing session and at the final testing session. There will most likely be a span of three months between these two dates.

If you are present at the testing sessions the FTDS may be completed at that time. These testing sessions will occur in the VA mobile simulator at a location near the combat veteran's house. Otherwise, we will provide instructions and a postage paid envelope for mailing the FTDS to the Principal Investigator, Dr. Sherrilene Classen.

The Principal Investigator listed in question 3 of this form and the research team conducting the research procedures described above will monitor how you do during the research. If you have any questions about the research procedures now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

It will take approximately 30 minutes to complete the FTDS for each of the two sessions. These sessions are about 3 months apart.

You will be asked to complete the FTDS measure two times over the course of the study:

- ☐ Completion of initial FTDS measure ~30 minutes
- ☐ Completion of follow up FTDS measure ~30 minutes

9. How many people are expected to take part in this research study?

Up to 260 caregivers/family members/friends from rural areas of North Florida and South Georgia are expected to participate in this study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

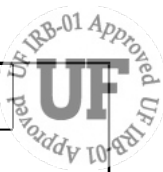
10. What are the possible discomforts and risks from taking part in this research study?

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed



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inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

Other possible risks to you may include: As part of filling out the FTDS measure , you may be asked to answer questions that make you uncomfortable. You can choose to not answer a question or questions and/or stop filling out the questionnaire at any time.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this consent form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of any new information that may become available and might affect your decision to remain in this study. This includes, but is not limited to, information that may affect your safety, well-being or medical care.

If you wish to discuss the risks or discomforts described above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 of this form.

11a. What are the potential benefits to you for taking part in this research study ?

There is no direct benefit to you from being in this study. You may learn more about the veteran's driving behaviors and skills.

11b. How could others possibly benefit from this study?

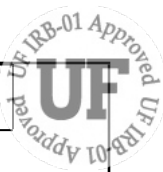
This study may show that specialized driving training and methods can help other combat veterans with driving and mobility problems.

In the future, we may be able to determine which types of driving recommendations, treatment and referrals will be best suited for combat veterans so that they can stay active and happy getting around in their communities in order to live a fulfilling life whether they drive or not.



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 Veterans Health System

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

The option to taking part in this study is doing nothing. If you do not want to take part in this study tell the Principal Investigator and do not sign this Informed Consent Form.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected will continue to be used to the extent that the researchers have used it in this research study.

13c. Can the Principal Investigator withdraw you from this study?

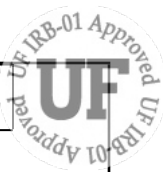
You may be withdrawn from the study without your consent for the following reasons:

- If you are unable or unwilling to participate in study tasks including participation in completion of the FTDS measure and/or final interview.



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WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

There will be no costs to you for any procedure, treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not being done only for this study (e.g., normal hospital and prescription expenses which are not part of the research study) will be charged to you or your insurance. These costs may not be charged if you are a veteran and you are being treated at the North Florida/South Georgia Veterans Health System (NF/SG VHS), however some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to VA-provided medical care and services that are not part of this study."

15. Will you be paid for taking part in this study?

Yes, you will be paid for participating in this research study through the University of Florida College of Public Health and Health Professions. You will be paid \$25 if you fill out the initial and final questionnaires (FTDS). Payment will be in the form of gift cards which will be given out after completion of the final questionnaire.

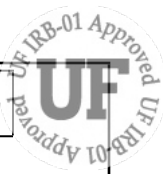
If you are paid more than \$75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to **nonresident aliens** must be processed through the University of Florida Payroll and Tax Services department. If the payments total \$600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: <http://privacy.ufl.edu/SSNPrivacy.html>.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.



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If you have any problems regarding your payment contact the study coordinator.

16. What if you are injured because of the study?

If you experience an injury or illness as a result of your participation in this VA approved research study, all medical treatment considered necessary by your physician (emergency as well as medical treatment beyond emergency) will be provided by the VA. There will be no cost to you, unless you fail to follow the directions of the study procedures. Care will be provided at a VA medical facility unless the VA medical facility is not capable of providing the care. If this occurs, you will be treated by a private facility or physician and the VA will pay the private facility or physician for the reasonable cost of your care. In some cases the VA may approve private care for a non-veteran.

If you do not follow study procedures, you may be treated by the VA on the basis of your veteran's eligibility. If you are not a veteran and have not followed study procedures the VA can only provide limited care at your expense.

No additional money has been set aside for pain, suffering or any money losses you may suffer during your treatment. You have not waived any legal rights by signing this form.

In the event of a research-related injury, have questions about any discomforts that you experience while participating in this study or if you experience an adverse reaction, please immediately contact the Principal Investigator listed in question 3 of this form during the day on 352-273-6883 and after business hours on 352-221-3041. If you seek emergency hospitalization in a private hospital because you are unable to come to the VA, have a family or friend contact your study doctor so that the VA can coordinate care with the private hospital.

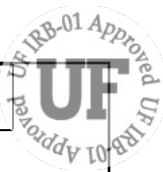
17. How will your privacy and the confidentiality of your research records be protected?

Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in



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research). Certain federal agencies such as the Office for Human Research Protections (OHRP), representatives of Department of Defense, the VA Office of Research Oversight (ORO), or the VA Office of the Inspector General (OIG), that oversee human subject research may also have the legal right to review your records. Otherwise your research records will not be released without your permission unless required by law or a court order.

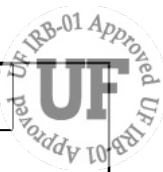
Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.



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SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how privacy will be protected:

 Signature of Person Obtaining Consent

 Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your privacy will be protected. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

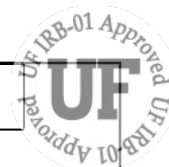
 Signature of Person Consenting

 Date



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Title of

Combat Veterans

Principal

Investigator: Sherrilene Classen, PhD.

North Florida/South Georgia

VAMC: Veterans Health System



INFORMED CONSENT FORM ***to Participate in Research***

INTRODUCTION

Name of person seeking your consent: _____

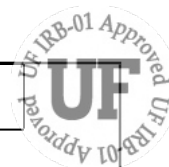
Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will also describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any VA or other benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, concerns, complaints, wish to discuss problems or talk to someone independent of the research staff, obtain information, or offer input, please call either of the following offices: (1) the University of Florida Institutional Review Board (IRB) office at (352) 273-9600; or (2) the North Florida/South Georgia Veteran's Health System Research Service Office at (352) 548-6069.



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Investigator:

Sherrilene Classen, PhD.

VAMC:

North Florida/South Georgia
Veterans Health System

GENERAL INFORMATION ABOUT THIS STUDY

Name of Participant ("Study Subject")

For PI Use:

Participant Social Security Number: _____

SSN should be written on this consent form by the research team prior to scanning into the VHA health record; if the subject does not have a VHA health record, this requirement is N/A.

2. What is the Title of this research study?

Effectiveness of a Driving Intervention on Safe Community Mobility for Returning
Combat Veterans

3. Who can you call if you have questions concerns, or complaints about this research study?

Principal Investigator: Sherrilene Classen, PhD 352-273-6883.

For emergencies, after hours or on weekends or holidays: Sandra Winter 352-214-3436. If you happen to not be able to reach anyone at the above numbers, please leave your name, message and a telephone number at one of the numbers and someone will call you as soon as possible.

Research Coordinator: 352-273-6024

4. Who is paying for this research study?

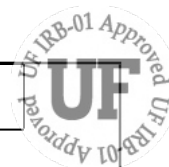
The sponsor of this study is Department of Defense

Funding Agency: Department of Defense – U.S. Army Medical Research and Material
Command - Telemedicine and Advanced Technology Research Center



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North Florida/South Georgia

VAMC: Veterans Health System

5. Why is this research study being done?

The purpose of this research study is to see if driving evaluation, driving training or education including ways to get around in the community help improve safety for combat veterans. We want to help combat veterans living with disabilities to be able to continue to drive safely as long as possible, using driving testing, training, and education. For veterans who do not drive or can no longer drive, education on other ways to get around in their community can help them stay active and get to places outside their home such as a store or the doctor's office. Inability to drive or loss of independence in community mobility may lead to depression, social isolation, or reduced health.

This project will address the community mobility needs of veterans including those living in rural areas that lack healthcare services. With our focus on independent and safe driving and independence in community mobility the study goals are:

- (1) Enhancing an occupational therapy driving intervention for returning combat veterans through the development of tailored simulator drives incorporating driving challenges (events to test mental and physical reactions of the driver) and trigger events (triggers are things like load noises or road debris that veterans have reported affect their driving).
- (2) Testing the simulator based driving intervention in comparison to an educational intervention. We want to know how the interventions work to reduce driving errors and impact citations, violations or other driving mishaps in the real world.
- (3) Determining if the interventions have an impact on the driver's community activity and satisfaction with life.

You are being asked to be in this research study because you are a combat veteran who has reported difficulty with some aspect of driving and an interest in intervention.

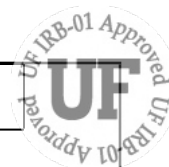
A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you.

At most, the Web site will include a summary of the results. You can search this Web site at any time.



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Sherrilene Classen, PhD.

VAMC: North Florida/South Georgia
Veterans Health System

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

Normal clinical care is medical or other treatment or services that you would receive even if you did not participate in this research study.

A typical driving evaluation includes tests of vision, thinking, and physical skills and an on-road driving test. Based on the results of your tests, the Driving Rehabilitation Specialist might (1) rate you as able to continue driving, (2) refer you for medical care that might help you drive safely, (3) provide training for your medical condition), and/or equipment to adapt your car and help you drive safely, or (4) recommend that you stop driving. If stopping driving was suggested then you would be given information about how to get around in your community without driving. At the driving evaluation you would have an eye test to make sure your vision meets state requirements. Your muscles and joints would be checked to for strength and ability to move. You would take some pencil-and paper tests, and a computer-based test for thinking skills and attention. These tests will take about 30-45 minutes to complete.

After the office tests, you would take a driving test in a car that has equipment, such as dual brake. The on- road driving test can take up to an hour in which you drive on different types of roads. Afterwards, the Driving Rehabilitation Specialist would talk to you about the results of the tests and tell you what to do to help improve your safety as you drive or get around in your community.

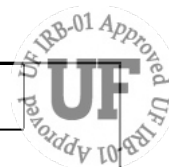
7. What will be done only because you are in this research study?

Before the driving tests or training or education sessions, you will first be called by study staff to see if you can be included in the study. After we know you are eligible and interested in the study, a written consent will be mailed to you and then reviewed during a phone appointment. We will ask you about days and times that will work for the initial testing session and set a time to go over the consent. For this study, we also ask you to provide information on a family member or friend who can answer questions about your driving. We will collect information regarding your driving history which for instance will include information on your previous moving violations, citations or traffic tickets; driving education class attended etc. Other information to be collected will be your basic driving skills (example question: "Does



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the driver have difficulty opening the car door?”), lastly your caregiver will rate your fitness to drive on a four point scale which will have questions such as “Is it difficult for driver to stay in the proper lane? etc.”

The study differs from a typical driving evaluation in that instead of 30-40 minutes of clinical testing there will be approximately 3 hours of testing prior to any driving. We will look at how you drive a driving simulator. It is mounted in the cargo section of a Dodge Sprinter van. Testing and training sessions will occur at safe and secure community locations such as the VA care location nearest your house, Smart house at Oak Hammock or your local library.

We will call you for a phone interview before any van testing is done. You will be asked about your general information, your health, medications, daily activities, driving habits, and life satisfaction. Then we will schedule your first session.

For female subjects, pregnancy tests (urine stick test) will be available to subjects who wish to confirm they are not pregnant prior to first and following study sessions.

After tests of vision, thinking and physical skills, you will take a driving test using the driving simulator. You will go through tasks on the simulator to get used to it (15-30 minutes) before beginning the actual driving test. As you get used to the simulator, driving will be on simple and slow roads. Then speed, road texture, curves and turns will be added to the scene as you drive. The driving simulation takes up to 1 hour to complete. As you use the simulator we will watch you and ask you how you feel. This is because some people get uncomfortable when they drive a simulator. See #10 below for more details.

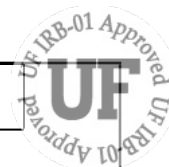
After your baseline testing, you will be assigned to one of two groups. One group will have driving training with an occupational therapist trained in driving rehabilitation, and one group with have driving education with a general driving safety professional. You will be placed in a group randomly or by chance selection. You will learn which group you are in after your baseline testing. Each intervention has five sessions of testing, training, or education. Testing sessions last 2-4 hours and training or education sessions last 60 to 90 minutes. Driving training is held as one-one sessions in the van and education is in a small group setting. A sub-set of thirty participants will have an on-road test in addition to simulated driving.

The Principal Investigator listed in question 3 of this form and the research team conducting the research procedures described above will monitor how you do during the research. If you have any questions about the research procedures now or at any time during the study, please contact one of the research team members listed



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in question 3 of this form. The Principal Investigator listed in question 3 of this form and the research team conducting the research procedures described above will monitor how you do during the research. If you have any questions about the research procedures now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

The first session will take up to four hours to complete questions about health and driving, tests of vision, thinking and physical skills and the simulator test. After the first session, you will be assigned by chance, like the flip of a coin, to one of two intervention groups. There will be two training or education sessions lasting one hour each. There are two post-tests that may take 3-4 hours.

Veterans' sessions are expected to take place over four to six months.

In the case of mechanical or computer breakdown, we will schedule a make up session to complete the testing. The make-up session will be scheduled at the earliest convenience of the testing team; this session will be set within 2 weeks of the original testing date.

9. How many people are expected to take part in this research study?

Up to 260 combat veterans from North Florida and South Georgia are expected to participate in phase 2 and 30 combat veterans in phase 1 of the study. An additional 260 caregivers will also participate in the study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

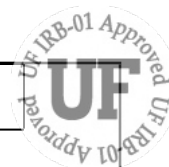
10. What are the possible discomforts and risks from taking part in this research study?

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a



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release could upset or embarrass you, or possibly even affect your insurability or employability.

At any time during the study, if the driving rehabilitation specialist has significant safety concerns about your driving, he/she will talk with you about the need for follow-up care. This may include sharing our safety concerns with health care providers at the VA, and arranging for a driving evaluation with an on-road driving test. The driving evaluation will be arranged by the research staff and offered at no cost.

You may refuse the follow-up care, however, study team members and the study medical monitor (a VA physician) will still discuss safety concerns about your driving and these concerns may be reported to the Department of Highway Safety and Motor Vehicles (DHSMV). The driving rehabilitation specialist or any other research team member does not have the authority to take away your license, only the DHSMV does. If you are reported, the DHSMV will send a letter within 30 days saying you may be unsafe to drive. The letter will tell you what to do and how much time you have to respond. They may send another form for your physician to fill out and return to them.

Other possible risks to you may include: Some people driving the simulator may feel symptoms like motion sickness. In this study we are taking steps to lessen the chance of simulator sickness including:

1. Driving the simulator was created to feel as close to life-like as possible. This helps reduce sickness.
2. We give you tasks so you get used to what it feels like to drive the simulator and slowly increase speed, road texture, curves and turns.
3. We watch you drive and ask you about how you feel, before, during and after any driving to check for simulator sickness. If you are more likely to feel sick, we will tell you and offer ways to reduce your risk. If at any point you tell us, or we can see that you don't feel well, your driving will be stopped. After a break and use of strategies such as cool air or ginger ale, we will discuss with you whether or not another attempt should be made at simulated driving. It is always your choice to stop driving or to withdraw from the study if simulated driving makes you uncomfortable.
4. We will ask you again how you feel after you are done driving to make sure that you are well enough to go back to activities before we end the session.

Informed Consent Form: Intervention testing

IRB Project #: 201500871

IRB Version: 04/25/2015

PI Version: 12/13/2016

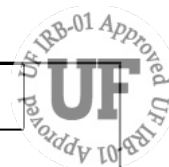
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Investigator:

Sherrilene Classen, PhD.

North Florida/South Georgia
VAMC: Veterans Health System

5. Set up of van to prevent/reduce sickness.

- The Dodge Sprinter van will be kept cool (under 75°) and a fan will be directed at the “driver”.
- Each driving task will not be more than 30 minutes.
- “Sick bags” will be on hand for use as needed.

6. If you feel sick after driving we will give you time to recover and will check how you feel every 10 minutes for up to 30 minutes, to see if you are feeling better. If you are not feeling better we will talk with you about options such as medical care or assistance with a ride home.

Risks for the on-road testing:

This study, for a sub-set of participants, involves on-road testing of driving fitness. You will drive a car equipped with a dual brake for this test. This car is owned and insured by the University of Florida. While driving in the car, you will be exposed to all the normal risks of driving such as a traffic collision/ crash or a driving citation. Any medical coverage for an injury that results from such an event will be handled as per Florida Law.

If the Driving Rehabilitation Specialist identifies significant safety concerns during on-road testing (such as lack of attention to driving, insufficient ability to see or react while driving), the Driving Rehabilitation Specialist will report the evaluation results to the medical monitor to determine if any medical or psychological care can be provided to help improve driving. The decision to report any driver to State of Florida Department of Highway Safety or Motor Vehicles Medical Advisory Board or state that issued the drivers' license will be based on the medical monitor's opinion.

If your driving is unsafe, your license may be revoked so that you can no longer drive. Only the State of Florida (or state issuing Driver's license) has the legal right to remove your driving privileges and they will not do this until after an investigation (obtaining medical records and, in some cases, an on-road driving assessment by a Department of Motor Vehicles driver's license examiner).

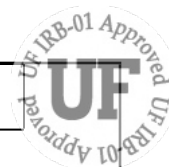
This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this consent form or the person reviewing this consent with you before enrolling in this or any other research study or project.



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VAMC:

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Throughout the study, the researchers will notify you of any new information that may become available and might affect your decision to remain in this study. This includes, but is not limited to, information that may affect your safety, well-being or medical care.

If you wish to discuss the risks or discomforts described above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 of this form.

11a. What are the potential benefits to you for taking part in this research study?

You may potentially benefit because the normal driving evaluation allows you to have your driving skills rated by a healthcare professional that specializes in driver rehabilitation. Feedback given by the driver rehabilitation specialist may improve your driving ability/safety

11b. How could others possibly benefit from this study?

We will learn about the driving performance, community activity, and life satisfaction of combat veterans who report driving difficulty post-deployment. We also learn about the impact of medical conditions common in veterans from conflicts in Iraq and Afghanistan such as Traumatic Brain Injury (mTBI), Post Traumatic Stress Disorder (PTSD) or Orthopedic injuries. Others will benefit if this information is used to help create driving programs for returning veterans and to improve driving evaluations.

The results of this study could also help physicians better identify which of their patients may be unsafe to drive. Some of these patients may be able to drive safely after the physician refers them to others for treatment (an eye doctor, for example) while those patients who are not safe to drive will be advised to stop. Removing dangerous drivers from our roads may make driving safer for everyone.

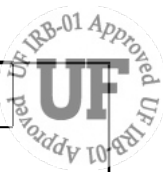
11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 may benefit if the results of this study are presented at scientific meetings or in scientific journals.



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Name:

Date

Effectiveness of a Driving Intervention on Safe Community Mobility for Returning
Title of Combat Veterans

Principal
Investigator:

Sherrilene Classen, PhD.

VAMC:

North Florida/South Georgia
Veterans Health System**12. What other choices do you have if you do not want to be in this study?**

The option to taking part in this study is doing nothing. If you do not want to take part in this study, tell the Principal Investigator and do not sign this Informed Consent Form.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected will continue to be used to the extent that the researchers have used it in this research study.

13c. Can the Principal Investigator withdraw you from this study?

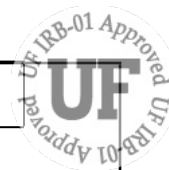
You may be withdrawn from the study without your consent for the following reasons:

1. You did not qualify to be in the study because you do not meet the study requirements.
2. If you did not follow the instructions given to you by the research study staff or investigators.



Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject
Name:

Date

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Title of Combat VeteransPrincipal
Investigator:

Sherrilene Classen, PhD.

North Florida/South Georgia
VAMC: Veterans Health System

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

No.

The Sponsor will only pay for medical services that you receive as part of your participation in this study as described in question 7 above.

There will be no costs to you for any procedure, treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not being done only for this study (e.g., normal hospital and prescription expenses which are not part of the research study) will be charged to you or your insurance. These costs may not be charged if you are a veteran and you are being treated at the North Florida/South Georgia Veterans Health System (NF/SG VHS), however some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to VA-provided medical care and services that are not part of this study."

15. Will you be paid for taking part in this study?

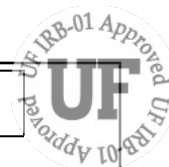
Yes, you will be paid for participating in this research study through the University of Florida College of Public Health and Health Professions. You will be paid \$50 for baseline testing. For each training or education session (up to two), you will be paid \$25. For the two post-tests, you will be paid \$50 for your participation in posttest 1 and \$100 for posttest 2. You will also receive at no charge a clinical and simulated driving evaluation by a Driving Rehabilitation Specialist (DRS). The DRS will also recommend a driving strategy for your personal skills and will also train driving skills, if need be. We will process payment for each session after it occurs. Payment will be in the form of gift cards which will be given out after each session, you will be paid only for the parts that you completed.

If you are paid more than \$75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to **nonresident aliens** must be processed through the University of Florida Payroll and Tax Services department. If the payments total \$600 or more in



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a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: <http://privacy.ufl.edu/SSNPrivacy.html>.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study coordinator.

16. What if you are injured because of the study?

If you experience an injury or illness as a result of your participation in this VA approved research study, all medical treatment considered necessary by your physician (emergency as well as medical treatment beyond emergency) will be provided by the VA. There will be no cost to you, unless you fail to follow the directions of the study procedures. Care will be provided at a VA medical facility unless the VA medical facility is not capable of providing the care. If this occurs, you will be treated by a private facility or physician and the VA will pay the private facility or physician for the reasonable cost of your care. In some cases the VA may approve private care for a non-veteran.

If you do not follow study procedures, you may be treated by the VA on the basis of your veteran's eligibility. If you are not a veteran and have not followed study procedures the VA can only provide limited care at your expense.

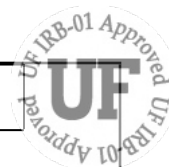
No additional money has been set aside for pain, suffering or any money losses you may suffer during your treatment. You have not waived any legal rights by signing this form.

In the event of a research-related injury, have questions about any discomforts that you experience while participating in this study or if you experience an adverse reaction, please immediately contact the Principal Investigator listed in question 3 of this form during the day on 352-273-6883 and after business hours on 352-221-3041. If you seek emergency hospitalization in a private hospital because you are



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unable to come to the VA, have a family or friend contact your study doctor so that the VA can coordinate care with the private hospital.

17. How will your privacy and the confidentiality of your research records be protected?

This is a collaborative study between the University of Florida (UF) and Veterans Affairs (VA). All VA data and records will be stored at the VA in a locked research office. Only de-identified data will be analyzed at the University of Florida. All hard copies (paper records) will be stored temporarily at UF during the study sessions and will be transferred to the VA for long-term storage. The final dataset will be stored on a protected server at the VA.

Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Certain federal agencies such as the Office for Human Research Protections (OHRP), representatives of Department of Defense, the VA Office of Research Oversight (ORO), or the VA Office of the Inspector General (OIG), that oversee human subject research may also have the legal right to review your records. Otherwise your research records will not be released without your permission unless required by law or a court order.

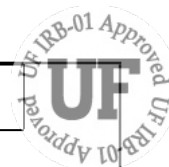
Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.



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SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how privacy will be protected:

Signature of Person Obtaining Consent

Date

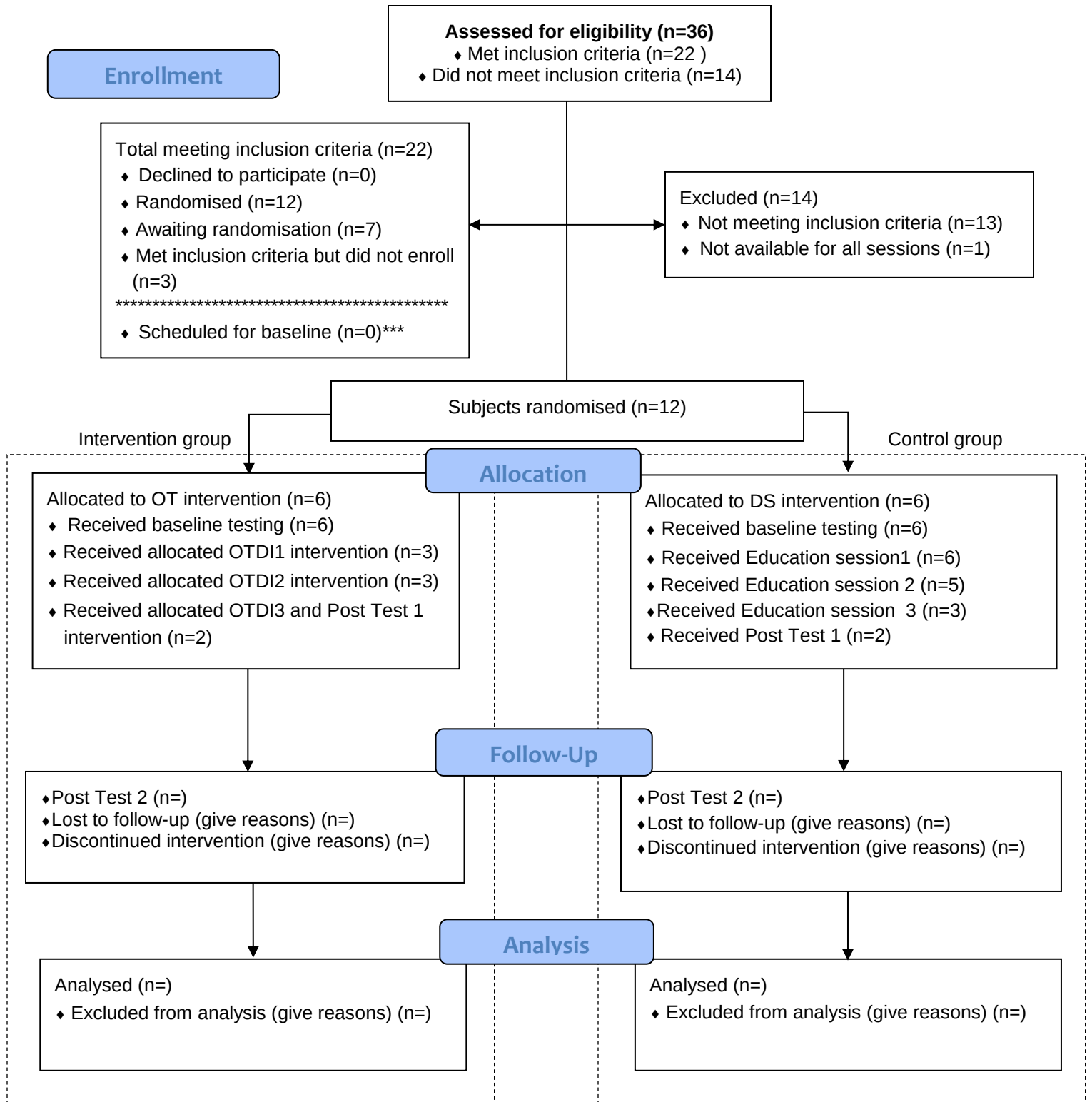
You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your privacy will be protected. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

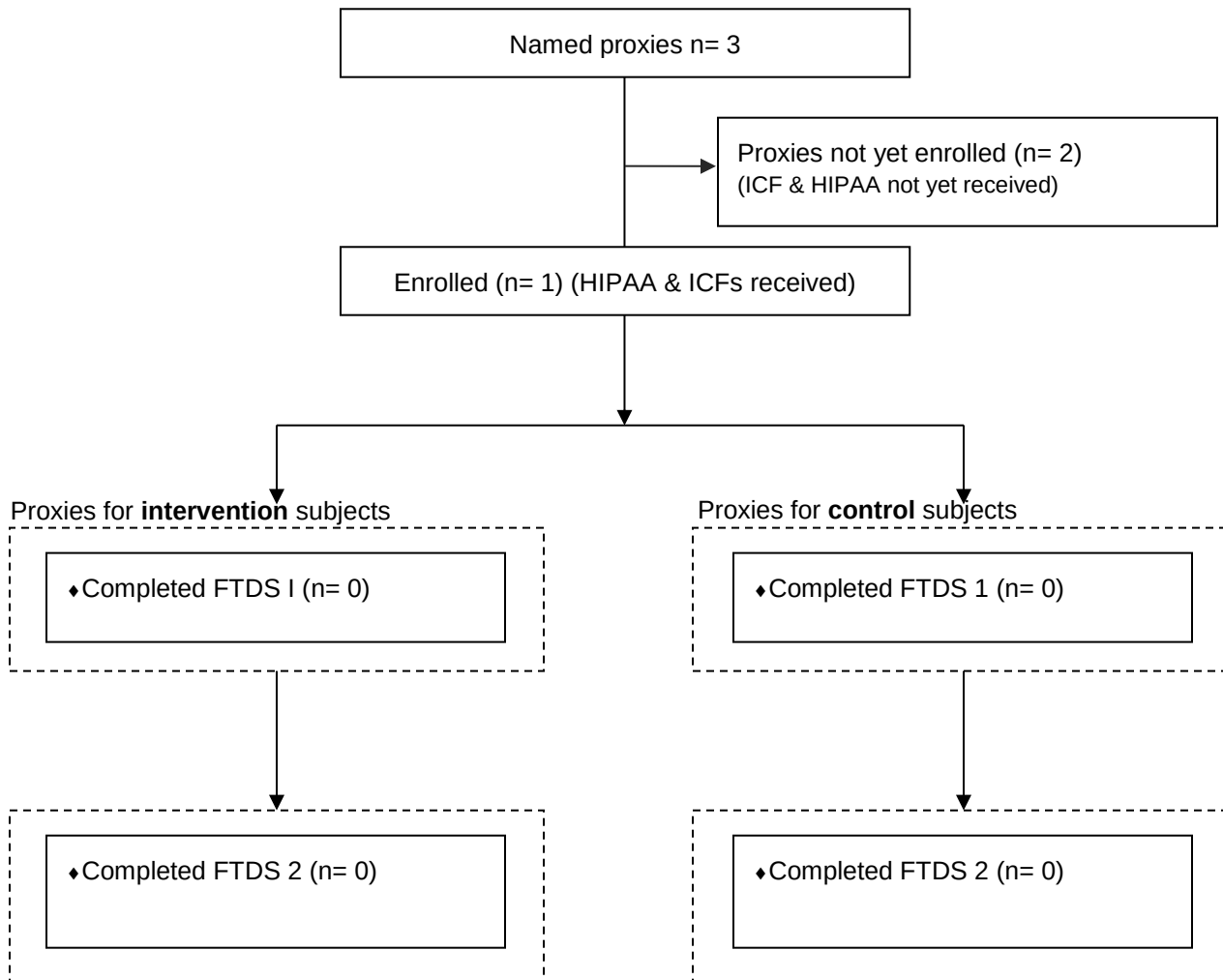
Signature of Person Consenting

Date

CONSORT Diagram for Subjects: Effectiveness study – 5.11.2018



Proxies



Driving Intervention for Returning Combat Veterans: Interim Analysis of a Randomized Controlled Trial

OTJR: Occupation, Participation and Health
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Abraham Yarney¹, Amanda Link Lutz⁴, Kyle Platek⁴, and Charles Levy²

Abstract

Increased crash incidence following deployment and veterans' reports of driving difficulty spurred traffic safety research for this population. We conducted an interim analysis on the efficacy of a simulator-based occupational therapy driving intervention (OT-DI) compared with traffic safety education (TSE) in a randomized controlled trial. During baseline and post-testing, OT-Driver Rehabilitation Specialists and one OT-Certified Driver Rehabilitation Specialist measured driving performance errors on a DriveSafety CDS-250 high-fidelity simulator. The intervention group ($n = 13$) received three OT-DI sessions addressing driving errors and visual-search retraining. The control group ($n = 13$) received three TSE sessions addressing personal factors and defensive driving. Based on Wilcoxon rank-sum analysis, the OT-DI group's errors were significantly reduced when comparing baseline with Post-Test 1 ($p < .0001$) and comparing the OT-DI group with the TSE group at Post-Test 1 ($p = .01$). These findings provide support for the efficacy of the OT-DI and set the stage for a future effectiveness study.

Keywords

veterans, simulation, driving, efficacy trial

Background

Motor vehicle crashes (MVCs) are one of the leading causes of death, injury, and hospitalization of returning combat veterans (CVs) from Operation Iraqi Freedom and Operation Enduring Freedom (OIF/OEF; Lew et al., 2011; Woodall, Jacobson, & Crum-Cianflone, 2014). MVCs are responsible for one third of all deaths of post-deployed CVs (Woodall et al., 2014). Increased MVCs have been associated with battlemind driving (defensive and offensive driving behaviors necessary for survival during combat) and diagnosis of polytrauma, traumatic brain injury (TBI), and/or post-traumatic stress disorder (PTSD; Cifu et al., 2013; Classen, Cormack, et al., 2014; Classen et al., 2011; Lew, Amick, Kraft, Stein, & Cifu, 2010). Efficacy studies testing interventions on veterans to reduce driving errors, the purpose of this study, are limited, yet critically needed (Classen et al., 2011).

prevails during civilian driving (Hoggatt et al., 2015; Lew et al., 2010). Aggressive driving tactics ingrained during combat training such as speeding, driving in the center of the road, and refusing to yield right-of-way and quick lane changes can be dangerous to the drivers, passengers, and pedestrians during civilian driving (Lew et al., 2010). CVs with multiple deployments are at even greater risk of crash involvement (Woodall et al., 2014). This may be due to battlemind driving habits, as well as the lack of mitigation strategies to combat such driving behaviors (Woodall et al., 2014). However, aside from potential causes such as being male, young, and having an "alpha male" role to fulfill during combat (Hannold, Classen, Winter, Lanford, & Levy, 2014, p. 1324), other documented causes (next discussed) include effects of polytrauma following blast

Literature Review

Battlemind Driving

Regardless of diagnoses, most CVs are at risk of impaired driving and crashes due to battlemind driving, that is, the defensive and offensive driving behaviors necessary for survival during combat, and although not necessary, still

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injuries (e.g., residual symptoms of a mild TBI or PTSD; Classen, Cormack, et al., 2014).

Polytrauma

Explosive injuries such as those caused by car bombs and improvised explosive devices (IEDs) are the most common causes of injury to CVs engaged in OIF/OEF conflicts (Cifu et al., 2013). Polytrauma, a condition predominately associated with OIF/OEF conflicts, is defined as “two or more injuries, one of which may be life threatening, sustained in the same incident that affect multiple body parts or organ systems and result in physical, cognitive, psychological, or psychosocial impairments and functional disabilities” (Department of Veterans Affairs, 2013, VHA Handbook 1172.0, p. 1) such as co-occurring TBI, PTSD, and musculoskeletal injury. Cifu and colleagues (2013) examined the records of all OIF/OEF and Operation New Dawn (OND) veterans from 2009 to 2011, and identified that 62.5% of the CVs with TBI also met the criteria for polytrauma. As such, polytrauma occurs in a significant cohort of the CVs.

TBI

TBI is caused by an external force affecting the head and results in alterations in brain function that can be long term or transient. Mild TBI, the signature injury of veterans from OIF/OEF, is defined as loss of/alterd consciousness of less than 30 min and a Glasgow Coma Scale of 13 to 15 (Centers for Disease Control and Prevention [CDC], the National Institutes of Health [NIH], the Department of Defense [DoD], & the Department of Veterans Affairs [VA] Leadership Panel, 2013). From 2000 to 2015, CVs have experienced more than 340,000 TBIs with the majority classified as mild TBIs (Defense and Veterans Brain Injury Center, 2016). TBI is a common combat-related injury and may have a negative impact on driving performance, including errors in speed regulation and/or difficulty with adjustment to stimuli (appropriate reaction to trigger stimulus; Classen et al., 2011).

PTSD

PTSD can occur after an individual experiences a terrifying event (National Institute of Mental Health [NIMH], 2016). Symptoms of PTSD include reliving traumatic experience(s) through flashbacks and dreams, avoidance and hyperarousal (NIMH, 2016). From 2000 through mid 2015, 138,971 returning CVs from OIF/OEF had a diagnosis of PTSD (Fischer, 2015). Driving can trigger CVs to experience flashbacks and react as if they were in the battlefield (Lew et al., 2010). CVs with PTSD are more likely to experience driving anxiety, particularly when civilian driving situations imitate dangerous battlefield situations, such as being tailgated (Zinzow, Brooks, & Stern, 2013). Hannold et al. (2014) reported that CVs with mild TBI and PTSD experienced a

range of emotional responses triggered by different driving situations. For example, traffic jams triggered an anxiety response; overpasses and intersections triggered a speeding response; and being cut-off from a roadway triggered an anger response. The combination of mild TBI and PTSD may further have a negative impact on the CVs' driving performance (Lew et al., 2010).

The need is to safely and accurately assess driving performance issues among these CVs and to provide them with intervention strategies that can curb battlemind driving behaviors, and the residual effects of polytrauma, mild TBI, and/or PTSD.

Driving Assessment and Intervention

Driving simulators, widely used to assess driving performance, are safe alternatives to the on-road assessment that may pose risks related to real-world circumstances, environments, and traffic conditions (Amick, Kraft, & McGlinchey, 2013; Classen, Cormack, et al., 2014; Classen et al., 2011). For example, Classen et al. (2011) conducted a study with 18 CVs from OIF/OEF with mild TBI and PTSD. These CVs made significantly more speeding and adjustment-to-stimuli errors and total number of driving errors than healthy controls. In follow-up driving simulator studies, researchers examined the benefit of an occupational therapy driving intervention (OT-DI) in reducing driving errors for a single subject (Classen, Monahan, Canonizado, & Winter, 2014), and among eight CVs diagnosed with orthopedic injury, mild TBI, PTSD, and/or polytrauma (Classen, Cormack, et al., 2014). These participants completed baseline testing (clinical tests of vision, cognition, and motor abilities, followed by a simulated drive) where seven driving errors were assessed, followed by three OT-DI sessions and a post-test (using the same procedure as baseline testing). The intervention utilized coaching strategies facilitated by the occupational therapist driving rehabilitation specialist (OT-DRS) to raise the CVs' self-awareness of driving errors (Session 1), visual-search skills training to detect critical roadway information (Session 2), and strategy implementation while driving with verbal commentary during the drive (Session 3). In the single-subject study, the overall driving errors were reduced post-intervention from 33 to 9 (Classen, Monahan, et al., 2014). The post-intervention results of the second study demonstrated a reduction ($p < .05$) in lane maintenance errors, as well as total number of driving errors (Classen, Cormack, et al., 2014). These two studies, although limited by small sample sizes and lack of control groups, suggest that a simulator-based OT-DI can provide a safe environment for testing and training of CV to reduce dangerous driving errors.

Purpose

The purpose of this study was to determine if an OT-DI (three 1-hr sessions as previously described) significantly

reduces the driving errors (type and number) in CV compared with a traffic safety education (TSE) in a randomized controlled trial. The finding of this research is critical for validating the efficacy of an OT-DI. If the OT-DI proves to be valid, this intervention could prevent needless driving-related injuries and deaths in CVs and others affected by reckless driving.

Method

This study was approved by the University of Florida's (UF) Institutional Review Board, the North Florida/South Georgia Veterans Affairs (VA) Research Committee, University of Western Ontario's Research Ethics Board as an exempt application, and the Department of Defense Human Research Protection Office (HRPO). This trial is registered with the ClinicalTrials.gov U.S registry (NCT02764983), <https://clinicaltrials.gov/ct2/show/NCT02764983>. All participants were informed of study risk and benefits through a verbal and written informed consent process. Privacy of all participants was maintained according to UF and Veterans Affairs (VA) procedures requiring their identity not be disclosed.

Design

We employed an unblinded parallel arm randomized controlled design with random allocation of participants to an intervention and control group.

Participants

Recruitment. CVs were recruited through in-person visits or flyers distributed in VA settings (Physical Medicine and Rehabilitation Clinic, OEF/OIF & Seamless Transition Program, Women's Clinic, and Community-Based Out-Patient Clinics). Likewise, recruitment was extended to veteran-centric community locations such as the Vet Centers, Veteran Student Groups, and the Wounded Warriors' TRACK Program in Jacksonville, Florida.

Sample size. We completed an interim (prior to completion of the study) analysis on 26 of the 60 participants. The final analysis has been powered ($\alpha = .05$, $\beta = 20\%$, effect size = .40) to determine if significant differences exist in the main dependent variable, that is, *number of driving errors*.

Random allocation. Based on the CONSORT 2010 Statement (Schulz, Altman, & Moher, 2010), we used a flow diagram to track and report our enrollment and group allocation (flow diagram not shown). We used a computer-generated block ($\times 6$) randomization scheme to assign participants to either an intervention or control group. At the time of this analysis, 26 participants (13 per group) who had completed study sessions through Post-Test 1

were included. The preliminary analysis was conducted to report progress on the actual study.

Inclusion criteria. CVs who have polytrauma (mild TBI/PTSD, traumatic limb amputation/fractures); drove prior to their injury/condition; have a valid driver's license; are community dwelling; have potential for following driving safety recommendations; scored no less than 24/30 on the Mini-Mental State Examination (MMSE); have the potential for following community integration strategies (MMSE 24/30); and who are able to participate in a driving evaluation as per self-assessment were included.

Exclusion criteria. CVs who have severe psychiatric (e.g., psychoses) or physical conditions (e.g., missing both arms and/or legs) that limit their ability to drive; have multiple psychotropic medications that may affect mental or physical (due to side-effects) functioning as per the consulting physician; have severe, irremediable medical conditions (e.g., severe TBI) as per the consulting physician; are pregnant females or those planning pregnancy as determined per self-report; and VA employees were excluded.

Procedure

After the participants provided informed consent, the team followed standardized protocols (Classen, Cormack, et al., 2014; Classen et al., 2011) to pursue with baseline testing. This included obtaining intake information, administering a clinical battery of visual (and other sensory), cognitive, and motor tests, and performing a standardized simulated driving assessment described below (Classen, Cormack, et al., 2014; Classen et al., 2011; Classen et al., 2015).

Driving simulator. The DriveSafety CDS-250 (Figure 1; DriveSafety, 2014) has a Ford Focus console configuration. The simulator's control devices include a steering wheel with active force feedback, automatic transmission, turn signals, and gas and brake pedals. The simulator's displays include a speedometer and a high-fidelity audio sound simulation of engine sounds. It has a 65° field of view with rendered scenes representing 110° horizontal view on tri-screen monitors, with side and rear view mirrors. The CDS-250 is equipped with record and playback functionality. The simulator is engineered in the back of the Dodge Sprinter van (Figure 2) and is used as a mobile simulator, meaning that the study team can access participants with transportation problems, or those who live in remote areas.

Acclimation scenario. All drivers were introduced into the simulator through an acclimatization process of three short (2-3 min) driving segments focused on operation of simulator controls, lane keeping, speed maintenance, and stopping. The acclimation process allowed CVs to physiologically adjust to the simulator.



Figure 1. Dodge sprinter van with the CDS-250 simulator engineered into the cab of the van.



Figure 2. DriveSafety CDS-250 high-fidelity driving simulator.

Driving scenario description

Residential and suburban drive scenario (6 min). This drive starts in a residential neighborhood on a narrow two-lane road with no markings and a 25-mph speed limit. This road section shows traffic, parked cars, trash cans at the curb, pedestrians, and features such as roadkill. The driver encounters four-way stop intersections, transitions to a rural two-lane road at 45 mph, and then to a commercial four-lane road at 35 mph with busy intersections. Three challenges occur requiring vigilance from the driver to avoid possible adverse events: (a) a pedestrian entering the crosswalk of the street that the driver is turning onto, (b) an unprotected left turn at an intersection with oncoming traffic in opposing lanes, and (c) sudden braking of a lead vehicle.

City and highway scenario (10 min). This drive starts in an urban area presenting multi-lane (4+) and narrow city streets, moderate traffic, and pedestrians. The drive proceeds to freeway driving with features such as roadside debris, a

disabled vehicle, and a tow truck. Three challenges occur; each requiring the vigilance of the driver to avoid possible adverse events. These are as follows: (a) a parked car pulling out in front of the driver, (b) the driver making an unprotected left turn, and (c) a pedestrian stepping from behind a parked car into the path of the driver.

Simulator Sickness Questionnaire (SSQ). Based on previous findings, we expected minimal occurrence of simulator sickness (SS; Classen, Cormack, et al., 2014). Still, every participant completed the SSQ before and after the acclimation and main drives (Kennedy, Lane, Berbaum, & Lilienthal, 1993). Following the standard protocol, we optimized the environment for mitigating or preventing symptoms of SS (Classen & Owens, 2010). Individual participants who showed an increase from baseline SS scores were offered rest breaks and were kept comfortable before they were dismissed from the intervention. Overall, the SS data are not further discussed because we had no significant findings within or between groups for SSQ scores.

We examined participants' demographics using standardized data collection sheets (Classen, Cormack, et al., 2014; Classen et al., 2011). The evaluators, one OT-CDRS and two OT-DRSs, administered the assessment and provided the driving intervention. Reliability among the three evaluators was established with 99.3% agreement among raters for the city/highway and 98% agreement for the residential/suburban conditions (Classen et al., 2015). The evaluators administered the visual, sensory, cognitive, and motor assessments. Consistent with the general driving literature, the MMSE that was used as a screening test of gross cognitive ability and CVs who scored less than 24 were excluded from participation (Crizzle, Classen, Bédard, Lanford, & Winter, 2012; Fox, Bowden, & Smith, 1998; Marottoli et al., 1998; Odenheimer et al., 1994; Trobe, Waller, Cook-Flannagan, Teshima, & Bieliauskas, 1996). Valid and/or reliable clinical tests included the Useful Field of View™ (UFOV), a visuo-cognitive test (Owsley et al., 1998); comprehensive vision tests, including visual acuity, peripheral vision, contrast sensitivity, stereopsis, depth perception, and lateral/vertical phorias, assessed with Optec 2500 (Stereo Optical Company Inc, 2009); and motor tests, including the finger-to-nose (Walker, 1990) and toe-tap tests (Molnar et al., 2007).

The evaluators assessed seven driving errors (type and number) with a standardized score sheet (Classen et al., 2011), while participants drove the simulator. These errors included speed regulation (maintaining the speed limit $\pm$ 5mph), lane maintenance (lateral position of the vehicle), visual scanning (during lane changes and at intersections), gap acceptance (determining safe timing for crossing in front of oncoming traffic), adjustment-to-stimuli (responding to road signs, pedestrians, or hazards), vehicle positioning (adequate space behind lead vehicle and stop line), signaling (correct use of turn signals), and total number of driving errors (sum of all the previous errors).

After baseline testing, the participants were randomly assigned to the balanced OT-DI (10 CVs with TBI/PTSD and three CVs with orthopedic conditions) and TSE group (seven with TBI/PTSD and six with orthopedic conditions). *Equipoise* (equality among two treatment arms and outcomes not known to the researcher), *concealed assignment* (group designation only disclosed at the end of study to the participants), and *intent to treat analyses* (concerted effort to mitigate attrition) were maintained.

Intervention group. The intervention group received the OT-DI consisting of three 1-hr sessions delivered by the evaluators. As discussed, Session 1 included the evaluator reviewing explicit driving errors with the CVs and suggesting tailored strategies to mitigate errors. For example, as the CV experienced hypervigilance in a stressful situation, such as encountering a dead animal in the simulated road scene, and performed a corresponding driving behavior, for example, speeding or wide swerving (to avoid the stimulus), the evaluator identified such behaviors and aberrant driving errors, discussed those with the CVs, and identified strategies to overcome these behaviors. In Session 2, the evaluators provided a visual-search training session to enhance the CV's ability to identify and react appropriately to critical roadway information (e.g., identifying brake lights and slowing down), while suppressing inappropriate or less critical roadway information (e.g., looking at billboards or brush, where snipers would hide in the battlefield, and as such not paying attention to the critical roadside information; Monahan, 2009). During Session 3, the CV drove the simulator, while incorporating the strategies from the previous two sessions and narrating the drive to provide an audible account of implementing the strategies. After the drive, each CV received targeted feedback from the OT-DRS.

Control group. The control group received 3 hr of TSE based on a Safety Council curriculum delivered initially by a traffic safety official and eventually via video. The traffic safety official (and video recordings) used a manualized curriculum with handbook for the Basic Driver Improvement course (National Traffic Safety Institute, 2011). These three 1-hr discussions focused on sharing traffic knowledge, vehicle safety, crash prevention, driving risk control/defensive driving, psychological factors, and driving under the influence of alcohol and substances.

Post-Test 1. Although the OT-DI group underwent Post-Test 1 immediately following Session 3, the TSE group had a time variation for participating in this session ($M = 16.5$ days, $SD = 17.72$ days). Post-Test 1 used the same standardized protocol outlined as for baseline testing. All CVs were reimbursed \$25 USD for the 1-hr training sessions but \$50.00 USD for the 3-hr baseline and post-test sessions.

Data Collection and Management

Data were collected by the evaluators, and a trained research assistant entered the data. These data were stored in a password-protected and secure server consistent with the security, privacy, and confidentiality policies of the participating university and the VA. All hard copies were stored in a fire-proof-locked filing cabinet in a locked research office at the VA. The study principal investigator performed regular data checks to identify and correct, with the research assistant, missing data or data entry errors. Data were typically entered within 2 to 3 days after the assessment or intervention session, and any discrepancies were resolved with the evaluator collecting the data.

Data Analysis

We used descriptive statistics to summarize nominal, ordinal, and numerical data. For between-group differences and after confirming uneven distribution (expected due to small sample sizes) with a Shapiro–Wilk test, the non-parametric Wilcoxon rank-sum test (between-group differences) was used to report on the difference in type and number of driving errors at baseline and Post-Test 1 for the OT-DI and TSE groups. For detecting between-/within-group differences with nominal/ordinal data, we used Fisher's exact test or the chi-square test, and a paired sample t test for determining the driving error difference scores of the means for baseline and Post-Test 1 for each group. We used IBM SPSS statistics Version 22 (IBM Corporation) for the analyses. Significance testing was conducted at $p \leq .05$, two tailed.

Results

The demographics characteristics for CVs ($N = 26$) by intervention ($n = 13$) and control groups ($n = 13$) demonstrated that CVs were all male, mostly White, with the majority having education past high school and being married. The mean age of participants was 38.69 ± 6.52 for the intervention group, and the mean age was 37.31 ± 10.21 for the control group. Most (>60%) of the CVs in each group did not report a crash in the last 3 years; however, self-reported citation rates in the last 3 years varied from 30% for the intervention group to 58% for the control group. We found no differences between any of the other variables in the between-group analysis. Moreover, the intervention group had exclusively White participants, while the controls had White (61.5%) and other (38.5%) racial categories. Based on the demographic variables, the findings suggest that the groups were not statistically significantly different.

No statistical differences existed for exposures between the two groups. However, the data suggested that the most common exposures (of injury) for both groups were mortars (61% for both groups), IEDs (61.5% for the intervention group; 38.5% for the control group), motor vehicle accidents

Table 1. Mean and Standard Deviation for Driving Errors at Baseline and Post-Test 1 for Combat Veterans ($N = 26$) by Intervention ($n = 13$) and Control ($n = 13$) Groups.

Driving error type	Intervention group		Control group	
	Baseline	Post-Test 1	Baseline	Post-Test 1
	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)
Speeding	12.31 (7.40)	4.92 (4.09)	13.00 (7.81)	10.08 (7.30)
Underspeeding	7.08 (6.10)	3.00 (3.67)	7.31 (8.56)	4.38 (4.92)
Overspeeding	5.23 (7.05)	1.92 (2.25)	5.69 (7.47)	5.69 (7.76)
Lane maintenance	12.23 (5.78)	6.15 (4.51)	9.92 (5.57)	8.69 (5.21)
Vehicle positioning	2.38 (1.89)	0.62 (0.65)	1.85 (1.68)	1.15 (1.14)
Gap acceptance	2.08 (1.04)	1.23 (1.30)	2.07 (1.32)	2.46 (1.05)
Signaling	1.62 (1.66)	0.38 (0.87)	3.08 (3.20)	2.54 (3.26)
Adjustment to stimuli	1.46 (2.26)	0.46 (0.78)	1.54 (1.39)	0.38 (0.51)
Visual scanning	0.38 (0.65)	0.00 (0.00)	0.54 (0.88)	0.15 (0.38)
Total driving errors	32.46 (11.60)	13.77 (9.44)	32.00 (12.41)	25.46 (13.26)

Table 2. Between- and Within-Group Differences in Driving Errors at Baseline and Post-Test 1 for Combat Veterans ($N = 26$) by Intervention ($n = 13$) and Control ($n = 13$) Groups.

Analysis	Test statistic	Visual scanning	Lane maintenance	Speeding	Vehicle position	Adjustment to stimuli	Signaling	Gap	Total driving errors
A1	W	159.50	167.00	151.00	156.50	126.50	166.50	161.50	145.00
	<i>M</i> (<i>SD</i>)	0.35 (0.69)	9.31 (5.33)	11.54 (7.56)	1.50 (1.45)	0.96 (1.18)	2.81 (3.18)	2.27 (1.19)	28.73 (13.02)
	<i>p</i> value	.26	.68	.22	.33	.01	.65	.48	.12
A2	W	149.50	125.00	127.00	130.00	152.00	128.00	145.50	110.00
	<i>M</i> (<i>SD</i>)	0.19 (0.49)	9.20 (5.94)	8.62 (6.96)	1.50 (1.65)	0.96 (1.73)	1.00 (1.44)	1.65 (1.23)	23.12 (14.08)
	<i>p</i> value	.10	.01	.01	.01	.20	.01	.11	<.001
A3	W	171.50	151.00	173.50	162.00	158.00	157.00	169.50	172.00
	<i>M</i> (<i>SD</i>)	0.46 (0.76)	11.08 (5.68)	12.12 (7.46)	2.12 (1.77)	1.50 (1.84)	2.35 (2.61)	2.08 (1.16)	32.32 (11.77)
	<i>p</i> value	.83	.22	.93	.50	.39	.35	.77	.87
A4	W	162.50	153.00	137.50	154.50	174.00	125.00	131.50	126.00
	<i>M</i> (<i>SD</i>)	0.08 (0.27)	7.42 (4.95)	7.50 (6.36)	0.88 (0.95)	0.42 (0.64)	1.46 (2.58)	1.84 (1.32)	19.62 (12.76)
	<i>p</i> value	.48	.26	.05	.31	.05	<.001	.02	.01

Note. A1 = Analysis 1; A2 = Analysis 2; A3 = Analysis 3; A4 = Analysis 4; W = Wilcoxon rank-sum test value; Analysis 1: Control baseline versus Control Post-Test 1; Analysis 2: Intervention baseline versus Intervention Post-Test 1; Analysis 3: Control baseline versus Intervention baseline; Analysis 4: Control Post-Test 1 versus Intervention Post-Test 1.

(53.8% for the intervention and control groups), and sniper fire (38.5% for the intervention group; 46.2% for the control group). Because no significant differences emerged for the exposures between the groups, we deduced that their exposure history was equivalent.

Clinical test results showed no significant group differences. The majority of participants had 20/20 vision when corrected, and intact depth perception. Mean cognitive scores from the MMSE were above 29 for each group, indicating virtually no cognitive deficits. Similarly, UFOV scores were Category 1 (lowest risk of potential future crash) for 92.3% of participants, again with no between-group differences. Mean UFOV sub-test scores of both groups were generally better than the cut-off scores (i.e., 500 ms). Visual processing impairment was only identified in two participants: one rated Category 2—low risk (intervention group) and the other rated Category 3—low to moderate risk (control group) for

MVCs. Coordination, measured by finger-to-nose test and toe tap, was within functional limits for the groups.

Table 1 displays the means and standard deviations for driving errors at baseline and at Post-Test 1 for the intervention and control groups. The baseline error with the highest mean scores across both groups was speed regulation, followed by lane maintenance. However, a post hoc analysis revealed that more underspeeding versus overspeeding errors occurred at baseline in the intervention ($M = 7.08$, $SD = 6.10$ vs. $M = 5.23$, $SD = 7.05$) and control groups ($M = 7.31$, $SD = 8.56$ vs. $M = 5.69$, $SD = 7.47$). For the intervention group, mean driving errors decreased for all error types at Post-Test 1. Likewise for the control group, except for gap acceptance, mean error scores decreased for all other driving errors at Post-Test 1.

Table 2 demonstrates the difference in mean driving errors made at baseline and after the intervention for both groups.

Comparisons to detect differences in mean scores, as a result of the intervention, were made four ways (control group against themselves at baseline and Post-Test 1; intervention group against themselves at baseline and Post-Test 1; control against intervention group at baseline; and the control against the intervention group at Post-Test 1), as indicated in the next section.

Analysis 1: Control Baseline Versus Control Post-Test 1

In comparing the mean errors by type made at baseline with the mean errors by type made at Post-Test 1 for the control group, only adjustment-to-stimuli errors decreased.

Analysis 2: Intervention Baseline Versus Intervention Post-Test 1

Upon comparing the mean errors by type made at baseline with the mean errors by type at Post-Test 1 for the intervention group, lane maintenance, speeding, vehicle position, signaling, and total driving errors decreased.

Analysis 3: Control Baseline Versus Intervention Baseline

Upon comparing the control group's baseline versus the intervention group's baseline, no significant findings emerged.

Analysis 4: Control Post-Test 1 Versus Intervention Post-Test 1

Upon comparing the control group's Post-Test 1 scores versus the intervention group's Post-Test 1 scores, the following findings emerged. Even though the intervention group made less adjustment-to-stimuli errors at post-test, compared with their own baseline, it was the control group that demonstrated a significant change (decrease) in these types of errors when compared with the intervention group. However, compared with the control group, the intervention group had reduced errors pertaining to speeding, signaling, gap acceptance, and the total number of driving errors.

Discussion

Similar to other CV studies that mainly report on male participants (Amick et al., 2013; Classen et al., 2011; Hwang, Peyton, Kim, Nakama-Sato, & Noble, 2014; Lew et al., 2011; Plach & Sells, 2013), this study had exclusively male participants. In addition, participants were mainly White and educated. Consistent with findings from Hoge et al. (2004), a considerable number of participants in both the intervention and control groups reported blast exposures due to mortars,

IEDs, and sniper fire. Yet different from the Hoge study, a large number of participants in this study also reported being exposed to motor vehicle accidents.

Clinical test results showed no significant group differences. Moreover, only very mild general cognitive impairment was detected. Thus, while participants reported clinical limitations consistent with their post-deployment status, overall they performed well in physical tasks needed for driving. The findings (Table 1) further show that for both groups, and between baseline and Post-Test 1, a reduction in mean driving error scores occurred. These findings suggest that the intervention group may have benefitted from the OT-DI, while the control group may have benefitted from the TSE sessions. However, when compared with the control group, the intervention group also displayed reductions in error scores across a larger number of driving errors. Interestingly, the speeding errors were related to underspeeding and not overspeeding, as previously noted in the literature (Amick et al., 2013; Classen et al., 2011). In discussion with the evaluators, it seemed that participants' speeding behaviors may have been influenced by being more careful while driving the simulator; however, we do not have empirical data to support this observation.

We also observed (Table 2) that only adjustment-to-stimuli errors reduced for the control group at Post-Test 1, while four types of errors, as well as the total number of driving errors, reduced for the intervention group. The findings from this interim analysis support the OT-DI as efficacious for reducing these types and numbers of errors after Post-Test 1. However, the sustainability and generalizability of this study finding can only be verified upon completion of the study and after the final analyses. Interestingly, no differences were detected between the controls and the intervention groups' baseline testing, suggesting that the groups were equivalent in making driving performance errors. The intervention group made more adjustment-to-stimuli errors when compared with the control group. Perhaps the TSE group heightened their awareness to general stimuli presented in the environment, thereby decreasing this error type. However, the intervention group who received targeted strategies for noticing critical roadway information may not have generalized such information to all environmental stimuli. Overall, the intervention group made fewer errors compared with the controls at Post-Test 1 in at least three (speeding, signaling, gap acceptance) of the driving errors, as well as the total number of driving errors.

This is significant in that speeding and gap acceptance are classified as critical driving errors, which increase the risk of being crash involved (Shechtman, Awadzi, Classen, Lanford, & Joo, 2010). Although signaling is not a critical driving error, one may suggest that it is a very important way of communicating intentions of maneuvers to drivers in lead or following vehicles, and as such communicates information to other road users. Lack of such communication may lead to traffic flow challenges.

Table 3. Between- and Within-Group Differences for Speeding Driving Errors at Baseline and Post-Test 1 for Combat Veterans ($N = 26$) by Intervention ($n = 13$) and Control ($n = 13$) Groups.

Analysis	Test statistic	Total speeding	Underspeeding	Overspeeding
Analysis 1	W	151.00	161.00	172.00
	M (SD)	11.54 (7.56)	7.00 (5.85)	5.70 (7.46)
	p value	.22	.47	.87
Analysis 2	W	127.00	144.00	155.00
	M (SD)	8.62 (6.96)	5.04 (5.35)	3.58 (5.40)
	p value	.01	.11	.30
Analysis 3	W	173.50	171.00	166.50
	M (SD)	12.12 (7.46)	7.19 (7.28)	5.46 (7.12)
	p value	.93	.83	.66
Analysis 4	W	137.50	167.50	148.00
	M (SD)	7.50 (6.36)	3.69 (4.31)	3.81 (5.92)
	p value	.05	.69	.16

Note. Analysis 1: Control baseline versus Control Post-Test 1; Analysis 2: Intervention baseline versus Intervention Post-Test 1; Analysis 3: Control baseline versus Intervention baseline; Analysis 4: Control Post-Test 1 versus Intervention Post-Test 1. W = Wilcoxon rank-sum test value.

Differences in the simulator protocols, heterogeneity among subjects, and categorization of driving errors limit direct comparison of study findings reported by Amick et al. (2013) with these findings. For example, Amick et al. measured speed with 10 sub-categories of error including “driving too slow”; yet in reporting the findings, speeding errors were reported collectively (i.e., underspeeding was not distinguished). However, the literature supports CVs making increased driving errors when compared with the general population (Amick et al., 2013); or as an outcome of “battle-mind” driving (Lew et al., 2010). But, our study shows (Table 1) that CVs are more prone to underspeeding in the driving simulator. This finding may be explained by more cautious driving behaviors when being evaluated, or as a result of “taking their time” as they acclimate to the simulator. Interestingly, no statistical significant differences exist between or within the intervention and control group if speeding is further analyzed in terms of over and under speeding (Table 3).

Limitations

The primary limitation of this study is the lack of blinding for evaluators, as they collected baseline and post-test data, as well as conducting the OT-DI, which may have biased and/or skewed the results. For the control group, the use of video to deliver content versus in-person delivery may have created a Hawthorne effect (i.e., observation, or lack thereof, affects performance). A learning effect may have been present for both groups because the driving scenarios used at baseline and post-tests were the same, and the presence of scripted events (e.g., a car pulling out) was not randomized. Therefore, participants could have anticipated the order of the hazards. That being said, both of the groups were exposed to this

aspect of the protocol, so it potentially did not benefit one group over another. The timing of Post-Test 1 was different for the two groups and resulted in the control group requiring additional time before this post-test could be conducted. Immediate evaluation of the intervention group as compared with (more than 2 weeks) delay could have significantly affected findings, especially as we do not yet have the evidence to demonstrate that the intervention group maintained improvements. Although we have randomized the allocation of participants to the OT-DI (10 CVs with TBI/PTSD and three CVs with orthopedic conditions) and TSE group (seven with TBI/PTSD and six with orthopedic conditions), the difference in the distribution of TBI/PTSD and orthopedic conditions between the groups, in this small sample, is problematic. Moreover, based on the results of this simulator study, no causal inferences can be made to on-road driving performance. As such, the data from the interim analysis need to be interpreted with caution.

Strengths

The OT-DI was focused on enabling CVs to assume their occupational roles in life, of which driving is a powerful facilitator. In this interim analysis of the clinical trial, we followed a blocked randomization scheme for participant allocation to group. Equivalence between groups existed at baseline, as evidenced by no significant differences in most demographics, exposures, clinical tests, and driving errors. Despite conversion to video delivery of the TSE, both the OT-DI and TSE were manualized and executed according to a standard procedure. Finally, this work builds on data from a study of driving performance of 18 CVs with TBI (Classen et al., 2011), a single-subject design study (Classen, Monahan, et al., 2014), and an earlier efficacy study (Classen, Cormack, et al., 2014). As such, the findings of this study further contribute to the temporal plausibility of our assessment and intervention work with returning CVs.

The results of these findings may influence future CV studies, guide policy regarding their driving needs, and inform clinicians for identifying at-risk CVs, as well as providing them with intervention strategies for improving driving performance. These findings are based on comparison data between baseline and Post-Test 1 of the two groups in our parallel arm design. To determine intermediate-term effects, subsequent analyses will compare groups based on results from post-tests 3 months after intervention. In addition, we have not yet addressed state records containing citations and violations that are representative of real-world driving. Such comparisons are planned for a future study.

Implications for Practice

Our study findings have the following implications for practice:

- This study and our prior research with veterans illustrate early empirical support for assessing and intervening with CVs, to reduce their driving errors on a simulator.
- The findings support an evidence-informed approach for using driving simulator-based assessment and interventions.
- The findings provide support for the utility and benefits of an OT-DI for CVs.

Research Ethics

Name of Institutional Review Board: University of Florida Institutional Review Board, Health Science Center Institutional Review Board (IRB)-01. Ethic Committee's reference No. 652-2011.

Declaration of Conflicting Interests

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Driving Intervention for Returning Combat Veterans: Interim Analysis of a RCT

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Introduction: Increased crash incidence in combat veterans' (CV) spurred traffic safety research. Previous driving studies (18 CV from OIF/OEF with mild TBI and PTSD) conducted on a driving simulator indicated that CVs made significantly more speeding, adjustment-to-stimuli and total number of driving errors compared to healthy controls. Researchers examined the benefit of an occupational therapy driving intervention (OT-DI) in reducing driving errors for a single subject and among eight CVs diagnosed with orthopedic injury, mild TBI, PTSD, and/or polytrauma. These participants completed baseline-testing (clinical tests of vision, cognition and motor abilities, followed by a simulated drive) where seven driving errors were assessed, followed by three OT-DI sessions, and a post-test. The intervention utilized: coaching strategies (Session 1); visual-search skills training (Session 2); and strategy implementation while driving with verbal commentary (Session 3). In the single-subject study, the overall driving errors were reduced post-intervention from 33 to 9. The post-intervention results of the second study demonstrated a reduction ($p < .05$) in lane maintenance errors and total number of driving errors. Despite limitations these two studies suggest fidelity and feasibility for a simulator-based OT-DI to reduce dangerous driving behaviors.

Methods: In this randomized controlled trial we conducted an interim analysis on the efficacy of a simulator-based OT-DI compared to Traffic Safety Education (TSE). During baseline and post-testing the OT-(Certified) Driver Rehabilitation Specialists measured clinical performance via a standardized battery of clinical tests and assessed driving performance errors on a DriveSafety CDS-250 simulator. The intervention group ($n=13$) received three OT-DI sessions as described above. The control group ($n=13$) received three TSE sessions addressing personal factors and defensive driving.

Results. Wilcoxon rank-sum analysis indicated that four (of seven) driving errors and the total number of driving errors were reduced for the OT-DI group from baseline to post-test 1 ($p < .0001$); and three (of seven) and the total number of driving errors were significantly reduced ($p = .01$) when comparing the OT-DI group to the TSE group at post-test 1.

Conclusion. These findings provide support for the efficacy of the OT-DI and set the stage for an effectiveness study.

Funding. The United States Department of Defense project # W81XWH-11-1-0454



Grounded Theory Informing a Driving Intervention Clinical Trial for Returning Combat Veterans

Sandra M. Winter, PhD, OTR/L

Mary Jeghers, MSOT, OTR/L

Emily Reid, MOT, OTR/L

2018 AOTA Annual Conference and Expo

Salt Lake City, Utah, April 19, 2018

Acknowledgements

Contributing Authors

- Sherrilene Classen, PhD, MPH, OTR/L, FAOTA, FGSA
- Sandra Winter, PhD, OTR/L
- Emily Reid, MOT, OTR/L
- Cassandra McGowan, BHS
- Mary Jeghers, MSOT, OTR/L
- Miriam Monahan, OTD, OTR/L, CDRS, CDI
- Abraham Yarney, ME
- Charles Levy, MD
- Elizabeth Hannold, PhD

Collaborating sites

North Florida/South Georgia Veterans Health System

Malcom Randall VA Medical Center

VA's Center of Innovation on Disability and Rehabilitation Research, Gainesville site, FL

Research Labs and Sites

I-MAP, University of Florida, USA

i-Mobile Research Lab, Western University, ON, Canada

VA Center of Innovation on Disability and Rehabilitation Research

Malcom Randall VA Medical Center

Funders

Veterans Affairs and the Department of Defense



Google: Images

Outline

- Significance
- Combat Veterans and Post-Deployment Driving
- Study Purpose
- Methods
- Grounded Theory Process
- Results
- Discussion
- Clinician takeaways



Significance

- **Driving as facilitator** - independence and participation
- Combat Veterans' medical conditions
- Increased risk of motor vehicle crash, injury or death¹
- Battlefield driving techniques
- **Driving difficulty** - impacts on community reintegration²
- Lack of published literature on Veterans' lived experiences
- Veteran perspective needed to inform behavioral intervention

¹ Woodall et al., 2014, *Am J Prev Med*.

² Possis et al., 2014, *Military Medicine*.

Purpose

Purpose – extend Hannold et al. (2013) conceptual framework

Research questions:

1. What are the lived experiences and perspectives of returning combat veterans on **driving difficulty** post-deployment and their intervention preferences?
2. How can their **perspectives inform** occupational therapy driving intervention?

Methodology

- IRB approval by all institutions
- Design - Qualitative Grounded Theory
 - Part of a larger mixed-methods study
- Sample
 - 5 Veterans with mTBI (VA study)
 - 8 Veterans with m/TBI and or orthopedic injury (DOD study)
- Setting – Large academic university with health science center & VA medical center
- Inclusion / Exclusion

Methodology

VA Study - Veterans with TBI in driving performance study ¹

- Semi-structured interviews with 5 participants
 - Digitally recorded, transcribed, and verified
- Examined driving pre and post-deployment
- Progressed from open to selective coding / Multiple iterations
- Published conceptual framework²

Methodology

DOD Study – Veterans with TBI or orthopedic injury in RCT of an occupational therapy driving intervention¹

- Moderated focus groups, digitally recorded, transcribed and verified (2 groups, each n=4)
- Examined Veteran's perspectives of behaviors, strategies, and intervention preferences
- Primarily selective coding, iterative team process

Methodology

- Use of qualitative software, NVivo (QSR International Pty Ltd. Version 11, 2015)
- Combine codebooks using constant comparative method¹
 - Thematic similarities/ differences
 - Patterns and relationships
- Iterative analysis including external review
- Expand conceptual framework / integrate new concepts

Results

Extended concepts

- Aggressive driving triggers
- Veteran strategies and competencies
- Driving response

New concepts:

- Hypervigilance and arousal level/ Continuum

Application of Occupational Therapy Models:

- Person-Environment-Occupation Model¹
- Environmental Press²

Results

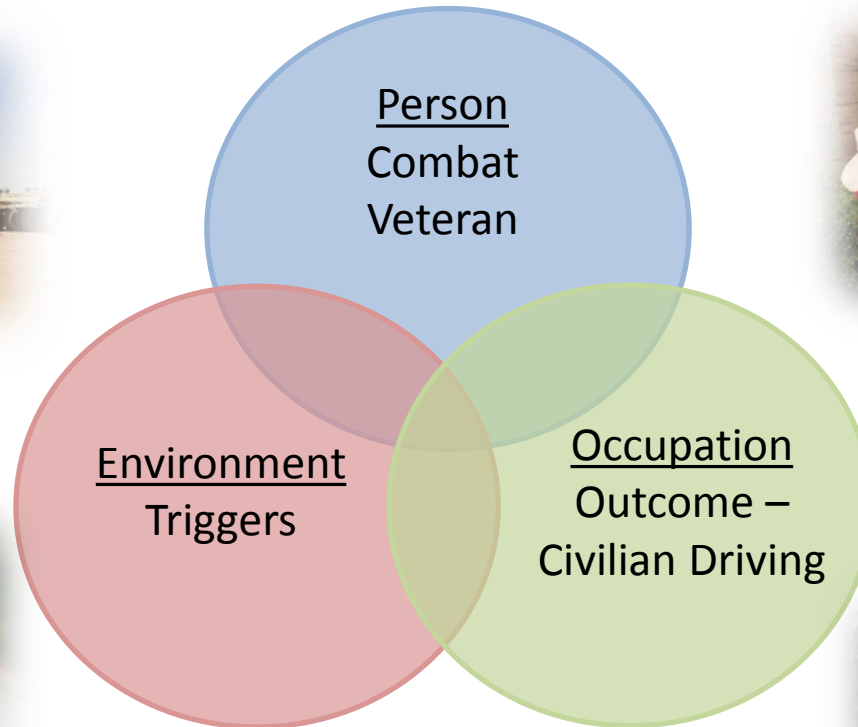
Person-Environment-Occupation (PEO) Model



U.S. Department of Defense Photo
Gallery



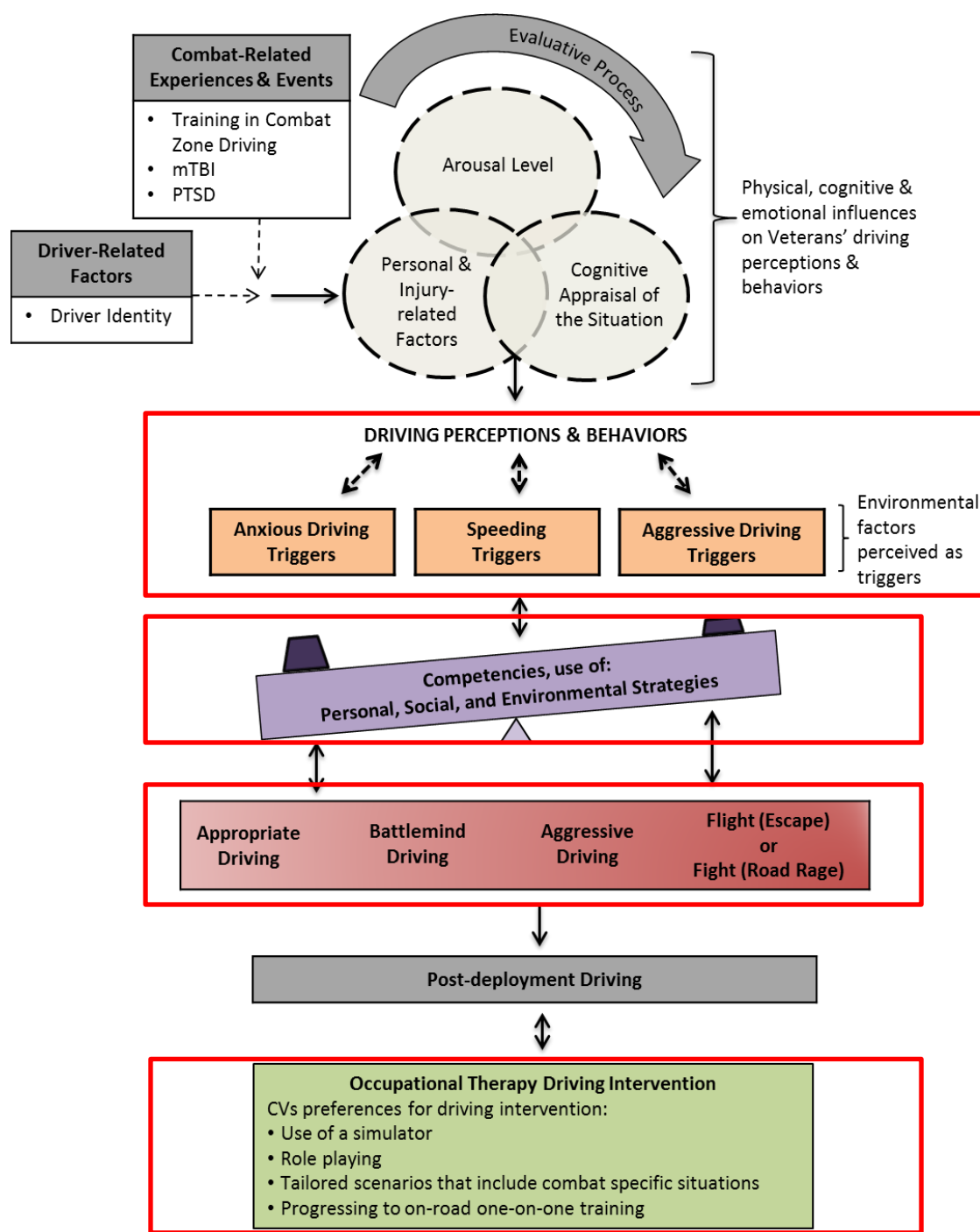
maafirm.com/library/tailgating-dangerous-driving-lawyer-fort-worth-personal-injury.cfm



U.S. Department of Defense Photo
Gallery



dailymail.co.uk/news/article-2877265/I-know-school-run-battle-ridiculous-Father-drops-children-morning-17-tonne-TANK.html



Results

Triggers

- Reclassified the code of *“Road-Rage Triggers”* with the code *“Aggressive Driving Triggers”*

“I try to just focus and...I’ll be talking to [other drivers], myself in the car ‘Get out of the way you dummy, you know you’re in the way’....And I hit the horn on them, and I hold the horn until they move, and then they move and I just keep cool.”

Results

Environmental Press: demand for a specific behavior

- The scale represents the environmental press on CVs competencies

Strategies

- Our data show that CVs attempt to adapt perceived threats before exhibiting a response

“I have to tell myself ‘I’m not there [in combat], I’m here [in the U.S.]....’ because if I don’t I’ll run you off the road in a minute.”

Results

Driving Response

- Responses to triggers could vary based on CVs arousal level
- Successful moderation may result in appropriate driving

**Appropriate
Driving**

**Battlemind
Driving**

**Aggressive
Rage**

**Flight (Escape)
or
Fight (Road Rage)**

"So I always convince [other drivers] they don't wanna be around me anymore... I just get very, very close to [their car]...really close to them..."

"I had one of my kids driving...and there's a semi-tractor trailer going by us and one of its' big tires blew out. They had to pull over and... I just sat for like two hours....it was like...'I don't care'. 'I'm not getting in that car.'"

Results

Occupational Therapy Driving Intervention

CVs preferences for driving intervention:

- Use of a simulator
- Role Playing
- Tailored scenarios that include combat specific situations
- Progressing to on-road one-on-one training

Discussion

- Explain based on first person perspective – Veterans' driving difficulties and triggers
- Integrate Person-Environment-Occupation Model as it relates to Veterans' driving performance
- Interpret our framework constructs through the lens of environmental press
- Reappraise Veterans' driving behavior as a continuum

Our studies illustrate **early empirical support** for a simulator-based **OT-DI** focusing on Veterans' driving performance.

The **evidence-informed driving simulator protocol** will help **OTs** inside and outside of VA and military settings to evaluate and treat driving performance deficits in Veterans.

Team Publications

- Classen, S., Levy, C., Meyer, D., Bewernitz, M., Lanford, D.N., Mann, W.C. (2011). Simulated Driving Performance of Returning Combat Veterans with MTBI: A pilot study. *American Journal of Occupational Therapy*, (65) 4, 419-427.
- Hannold, E. M., Classen S., Winter S., Lanford, D. N., Levy, C. E. (2014). Exploratory pilot study of driving perceptions among OIF/OEF Veterans with mTBI and PTSD. *Journal of Rehabilitation Research & Development*, 50(10):1315–1330.
- Classen, S., Cormack, N. L., Winter, S. M., Monahan, M., Yarney, A., Lutz, A. L., & Platek, K. (2014). Efficacy of an occupational therapy driving intervention for returning combat veterans. *OTJR: Occupation, Participation, and Health*, 34(4), 177-182.

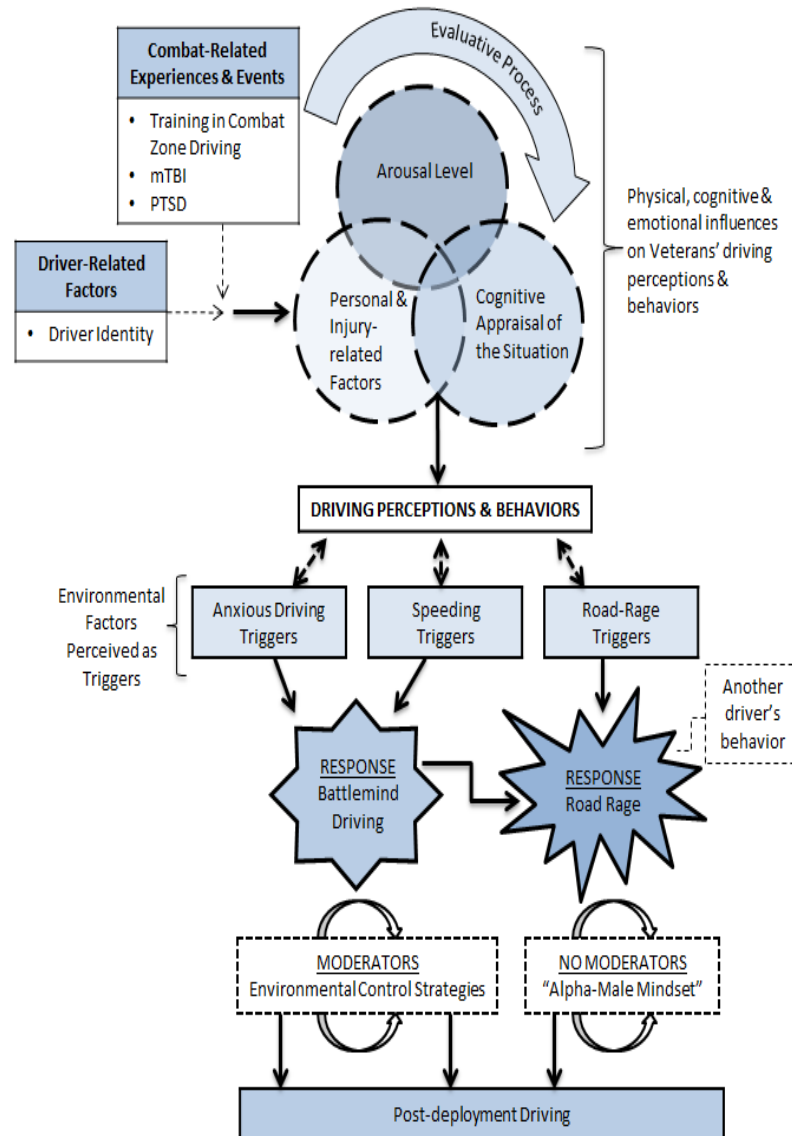
Questions

Contact info - Sandra Winter, PhD, OTR/L

- smwinter@phhp.ufl.edu



Initial Conceptual Framework





Mixed-methods Approach to Develop an Occupational Therapy Driving Intervention for Returning Combat Veterans

Presenter: Sherrilene Classen, PhD, MPH, OTR/L, FAOTA, FGSA,
Sandra Winter PhD, OTR/L, Mary Jeghers, MSOT, OTR/L,
Luther King, Dr.OT, CDRS, CDI, OTR/L, Katelyn Caldwell, BHS student

Contributors: Abraham Yarney, MS
Charles Levy, MD

Acknowledgements

Academic Institution

University of Florida, USA

Funders

The United States Department of Defense Project W81XWH-11-1-0454.

PI: Classen 10/01/2012-08/21/2013

PI: Winter 8/22/2013-07/01/2017)

Collaborating sites

North Florida/South Georgia Veterans Health System

Malcom Randall VA Medical Center

VA's Center of Innovation on Disability and Rehabilitation Research, Gainesville site, FL

Research Labs

I-MAP, University of Florida, USA

i-Mobile Research Lab, Western University, ON, Canada

Collaborators

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Students

Post-Docs

Doctoral

Honours BHS

Research Assistants



Google: Images

Sherrilene Classen, PhD, MPH, OTR/L, FAOTA, FGSA

HISTORICAL OVERVIEW

Background

Classen, S., Levy, C., McCarthy, D., Mann, W.C., Lanford, D.N., & Waid-Ebbs, J.K. (2009). Traumatic Brain Injury and Driving Assessment: **An Evidenced Based Literature Review**. *AJOT*, 63 (5), 580-591.

Classen, S., Levy, C., Meyer, D., Bewernitz, M., Lanford, D.N., Mann, W.C. (2011). Simulated Driving Performance of Returning Combat Veterans with MTBI: **A pilot study**. *AJOT*, (65) 4, 419-427.



Driving Errors:

- Speeding
- Adjustment-to-stimuli
- Total number driving errors



1. Classen et al. (2014). *OTJR*
2. Classen et al. (2014). *AJOT*

Video of Simulator

The slide features a dark blue header bar at the top. Below it, there are three horizontal bars of varying shades of blue: a medium blue bar, a darker blue bar, and another medium blue bar, all spanning the width of the slide.

Sandra Winter PhD, OTR/L

HANNOLD, E. M., CLASSEN S., WINTER S., LANFORD, D. N., LEVY, C. E. (2014). EXPLORATORY PILOT STUDY OF DRIVING PERCEPTIONS AMONG OIF/OEF VETERANS WITH MTBI AND PTSD. *JOURNAL OF REHABILITATION RESEARCH & DEVELOPMENT*, 50(10):1315–1330.

Qualitative Methods and Driving

- Mixed methods
- Complexity of driving behavior
 - Conscious actions
 - Subconscious actions
 - Reacting to physical and social environment
- Contribution to intervention planning
- Returning combat Veterans
 - Motor vehicle crash / top cause of death
 - Community reintegration / life roles

OEF/ OIF Deployment

- Operation Enduring Freedom (OEF) - 2001
- Operation Iraqi Freedom (OIF) - 2003
- Operation New Dawn (OND) - 2011
 - 2.6 Million Deployed
 - Estimated 6800 Fatalities
 - Estimated 52,000 Injured

<http://www.defense.gov/news/casualty.pdf>



Retrieved from <http://www.defense.gov/multimedia/>

Deployment

- Ingrained training for combat zone
 - “Don’t back up. If there’s an ambush, go through it... If there’s an obstacle... you go around it. If a car, all of a sudden pulls in front of you and breaks down, you don’t stop...” (P1)
- Exposures
 - Blast Exposure
 - Crash
 - Threats from Insurgents
- Medical Conditions



Retrieved from: www.defenseimagery.mil

Methods

- OEF/OIF Veterans' Driving Perspectives
 - Five participants from a larger study by Classen et al.
 - In-depth interviews / grounded theory approach
 - Concepts
 - Driver identity
 - Combat-related experiences and events
 - Impact on CVs' driving perceptions
 - Triggers
 - Anxious driving triggers
 - Speeding triggers
 - Road-rage triggers
 - Behaviors
 - Strategies to manage their driving behaviors

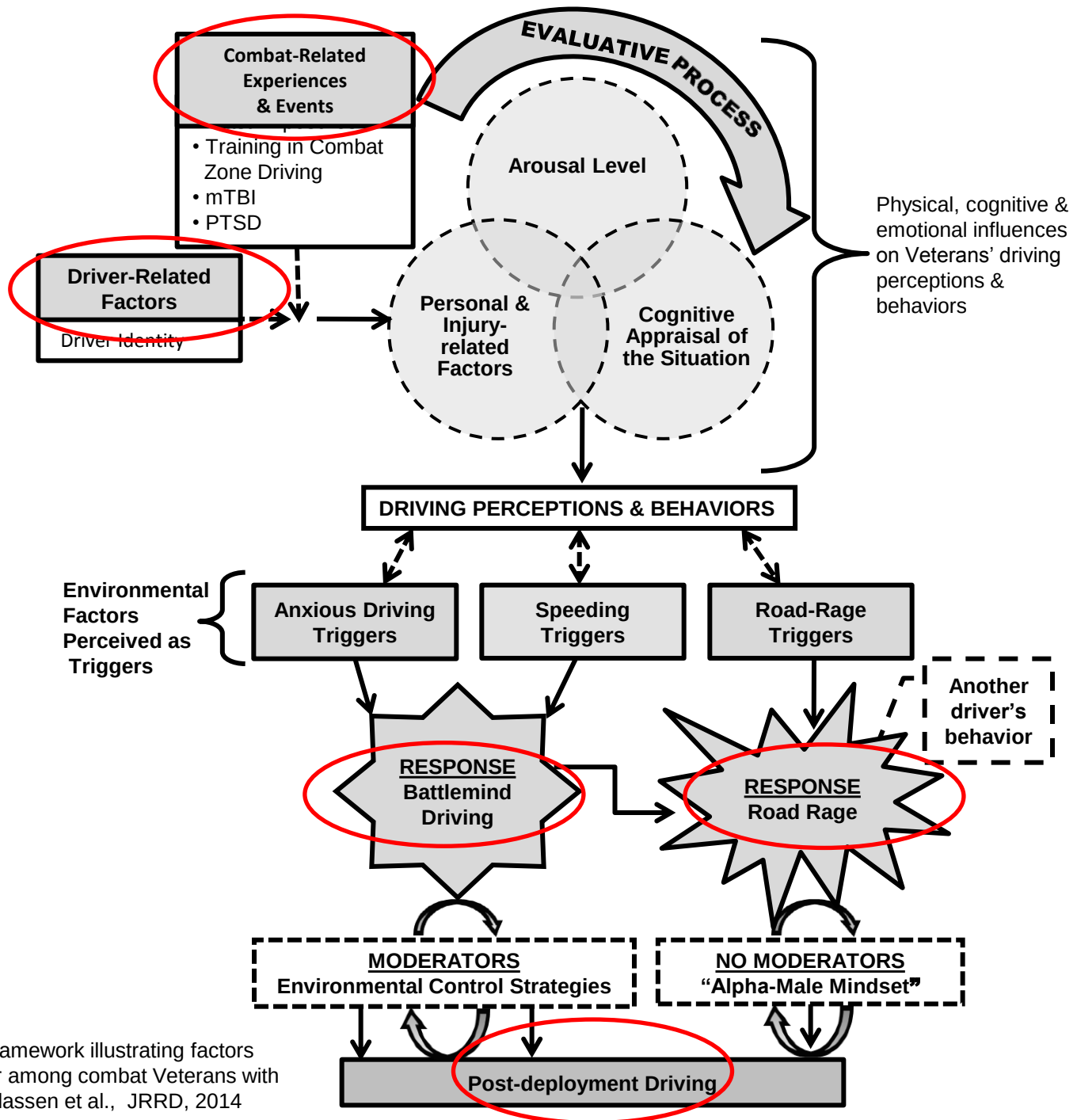
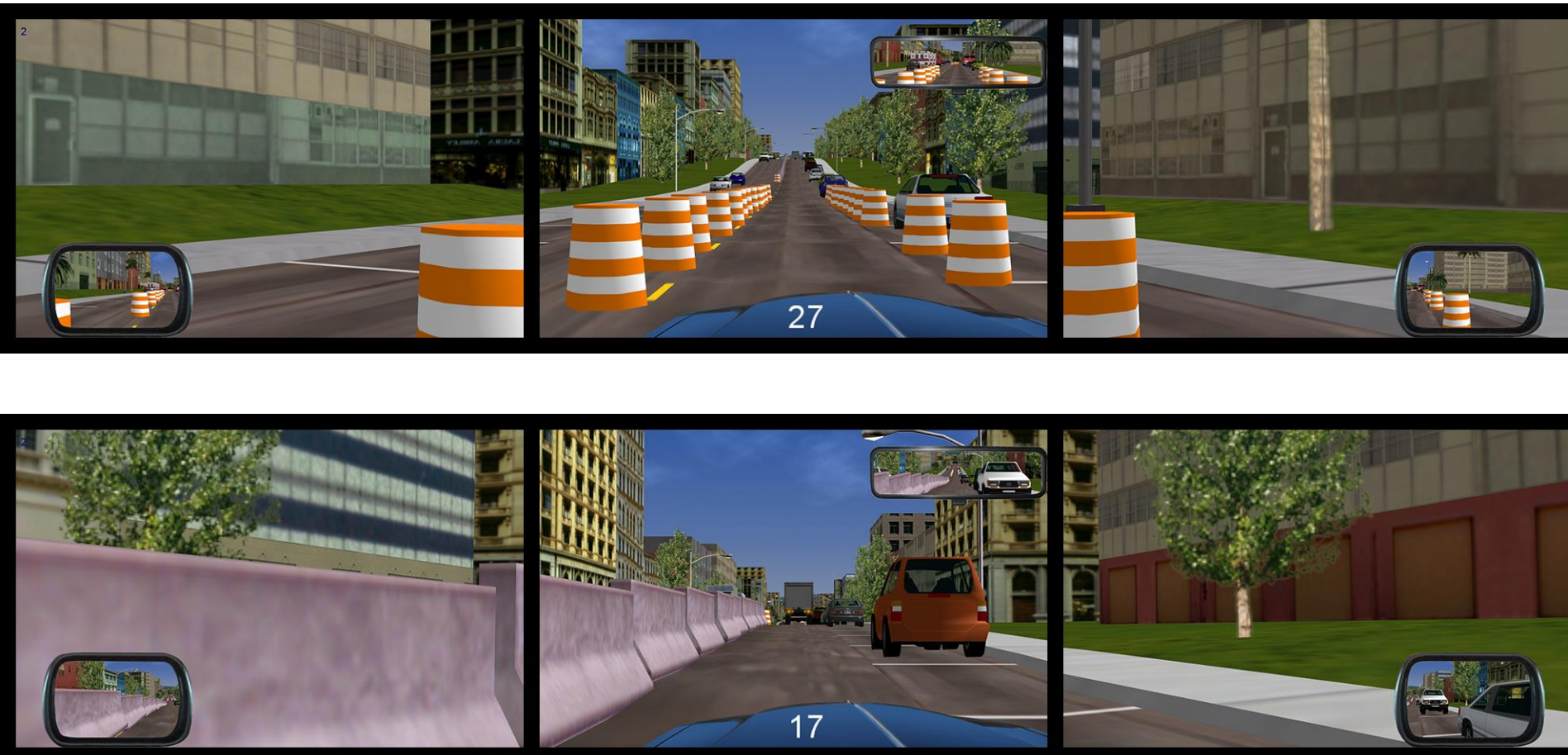


Figure 1. Conceptual framework illustrating factors affecting driving behavior among combat Veterans with mTBI/PTSD, Hannold, Classen et al., JRRD, 2014

Post-Deployment Results

- Perceived threats / triggers
- Altered perception of environment and social interactions (e.g. car blocking ingress/egress)
- Reinforcing self-talk
 - “...when I first got home... you couldn’t me on the road if you paid me. ...it took me a good two or three years before I started becoming a little more comfortable on the roads. But I finally had to tell myself “I’m not there” [Iraq].”
- Reactions to triggers
- Range from mild reactions to flashbacks

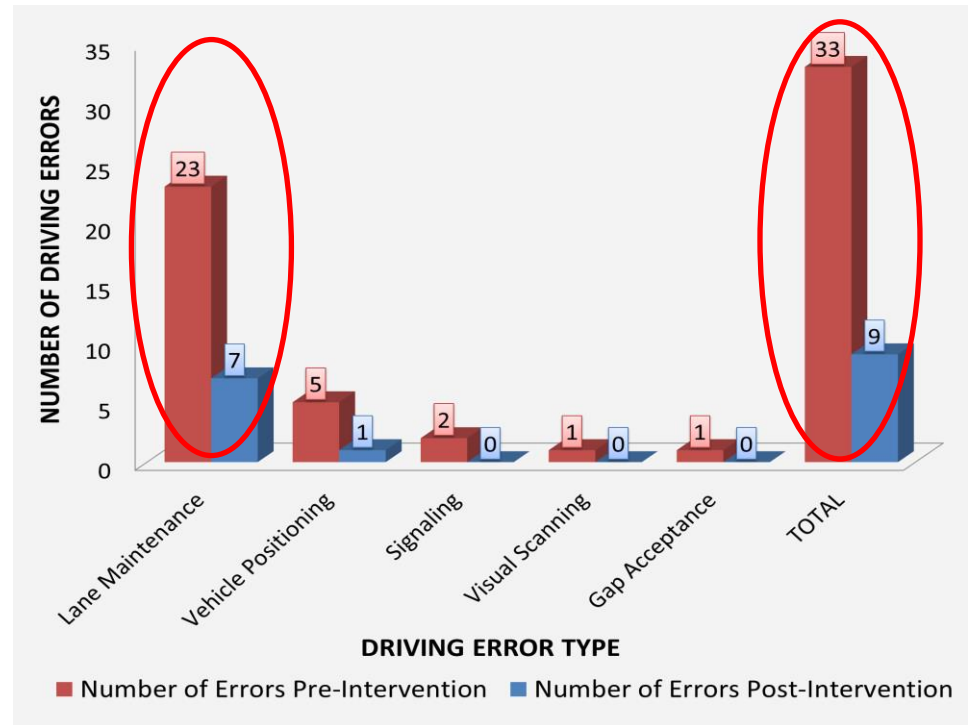
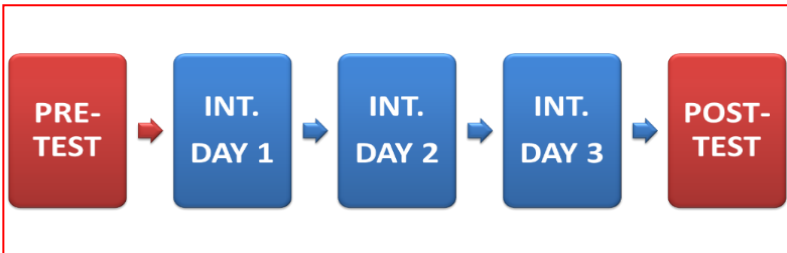
Scenario Development



Background

Determinants: Battlemind driving and Road Rage → Dangerous Driving Behaviors
Active Ingredients: Meta-cognitive, Visual search, Adaptive strategies, Task Performance

Classen, S., Monahan, M., Canonizado, M., & Winter, S.M. (2014). An Occupational Therapy Driving Intervention's **Utility for a Combat Veteran**. *AJOT*, 68(4), 405-411.



Conclusion: 5/5 driving errors improved, suggesting clinical significance of the OT-DI for this combat veteran

Background

Classen, Cormack, Winter, et al. (2014). Efficacy of an Occupational Therapy Driving Intervention for Returning Combat Veterans. *OTJR*, 34(4), 176-182.

N= 8: Pre and Post-test

- Lane maintenance (p=.05)
- Visual scanning (p=.06)
- Total # of driving errors (p=.03)



US Department of Defense (PI: Winter; Co-PI: Classen)

Cost: \$ 1,844,451.00

01 April 2015 – 30 March 2019

Effectiveness Trial of a Driving Intervention on Safe Community Mobility for Returning Combat Veterans

Mary Jeghers, MSOT, OTR/L

HANNOLD ET AL. (2014) GROUNDED THEORY FRAMEWORK EXPANSION

History

- TBI and PTSD study with 5 semi-structured interviews transcribed → codebook → Hannold et al. (2014) grounded theory framework
- 2 Focus groups → transcribed → thematic analysis → codebooks
- Combination of 3 previously developed codebooks → thematic analysis → iterative process to refine initial framework

Purpose

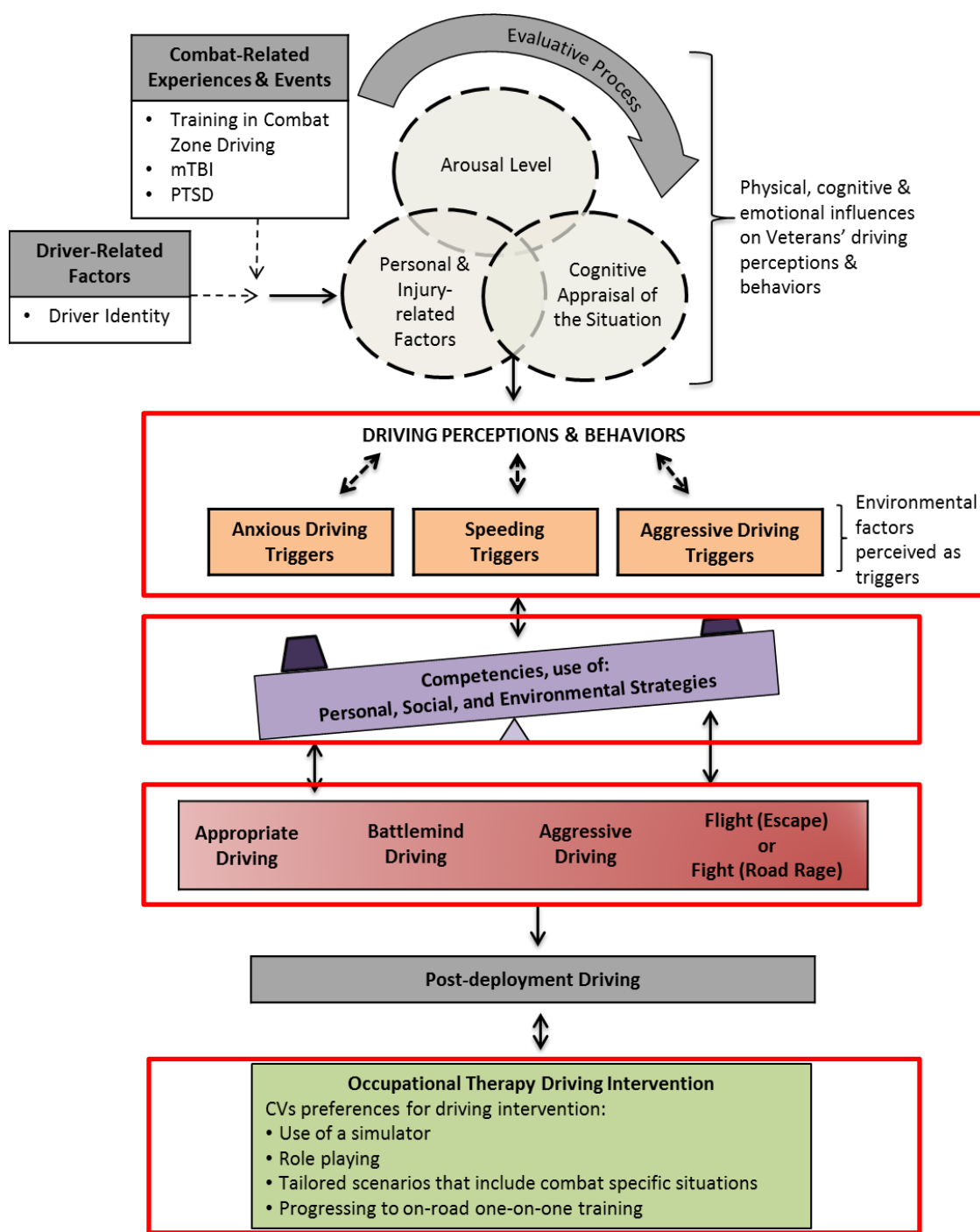
- Extend the current conceptual model of factors affecting driving behavior among CVs through the integration of findings from two moderated focus groups

Methods

- Use of qualitative software, Nvivo (QSR International Pty Ltd., Version 11, 2015)
- Combine codebooks using constant comparative method
 - Thematic similarities/differences
 - Patterns and relationships
- Iterative analysis including external review
- Expansion of conceptual framework/integrate new concepts

Results

- Extended concepts
 - Aggressive driving triggers
 - Veteran strategies and competencies
 - Driving response
- New concepts
 - Environmental Press
 - Hypervigilance and arousal level/continuum



Results

Triggers

- Reclassified the code of *“Road-Rage Triggers”* with the code *“Aggressive Driving Triggers”*

“I try to just focus and...I’ll be talking to [other drivers], myself in the car ‘Get out of the way you dummy, you know you’re in the way’....And I hit the horn on them, and I hold the horn until they move, and then they move and I just keep cool.”

Results

Environmental Press: demand for a specific behavior

- The scale represents the environmental press on CVs competencies

Strategies

- Our data show that CVs attempt to adapt perceived threats before exhibiting a response

“I have to tell myself ‘I’m not there [in combat], I’m here [in the U.S.]....’ because if I don’t I’ll run you off the road in a minute.”

Results

Driving Response

- Responses to triggers could vary based on CVs arousal level
- Successful moderation may result in appropriate driving

**Appropriate
Driving**

**Battlemind
Driving**

**Aggressive
Rage**

**Flight (Escape)
or
Fight (Road
Rage)**

"So I always convince [other drivers] they don't wanna be around me anymore... I just get very, very close to [their car]...really close to them..."

"I had one of my kids driving...and there's a semi-tractor trailer going by us and one of its' big tires blew out. They had to pull over and... I just sat for like two hours....it was like...'I don't care'. 'I'm not getting in that car.'"

Results

Occupational Therapy Driving Intervention

CVs preferences for driving intervention:

- Use of a simulator
- Role Playing
- Tailored scenarios that include combat specific situations
- Progressing to on-road one-on-one training

Discussion

- Better reflects CVs lived experiences and factors that underlie decision making while driving
- Inform clinical work with CVs who are experiencing driving difficulty, including driving interventions

Sherrilene Classen, PhD, MPH, OTR/L, FAOTA, FGSA

CLASSEN, S., WINTER, S.M., MONAHAN, M., LUTZ, A., PLATEK, K., & YARNEY, A. (2017). DRIVING INTERVENTION FOR RETURNING COMBAT VETERANS: INTERIM ANALYSIS OF A RANDOMIZED CONTROLLED TRIAL. *OTJR*. 37(2), 1-10.

Research Question

Can an OT-DI significantly ($p < .05$) reduce driving errors (number and type) in CVs from OEF/OIF with *polytrauma*, when compared to Traffic Safety Education (TSE)?

Polytrauma (Conceptual definition)³

- Two or more injuries to one physical region or organ system
- One of which may be life threatening.
- Result in physical, cognitive, psychological impairment and functional disability.

Polytrauma (Operational definition)

- Mild Traumatic Brain Injury
- Post Traumatic Stress Disorder
- Traumatic limb amputation/ fractures
- Result in functional disability



Methods

Study Approval

- University of Florida's (UF) Institutional Review Board: *IRB-01 Full Board Review*
- North Florida/South Georgia, Veterans Affairs (VA) Research Committee
- Department of Defense Human Research Protection Office (HRPO)

Study Registration

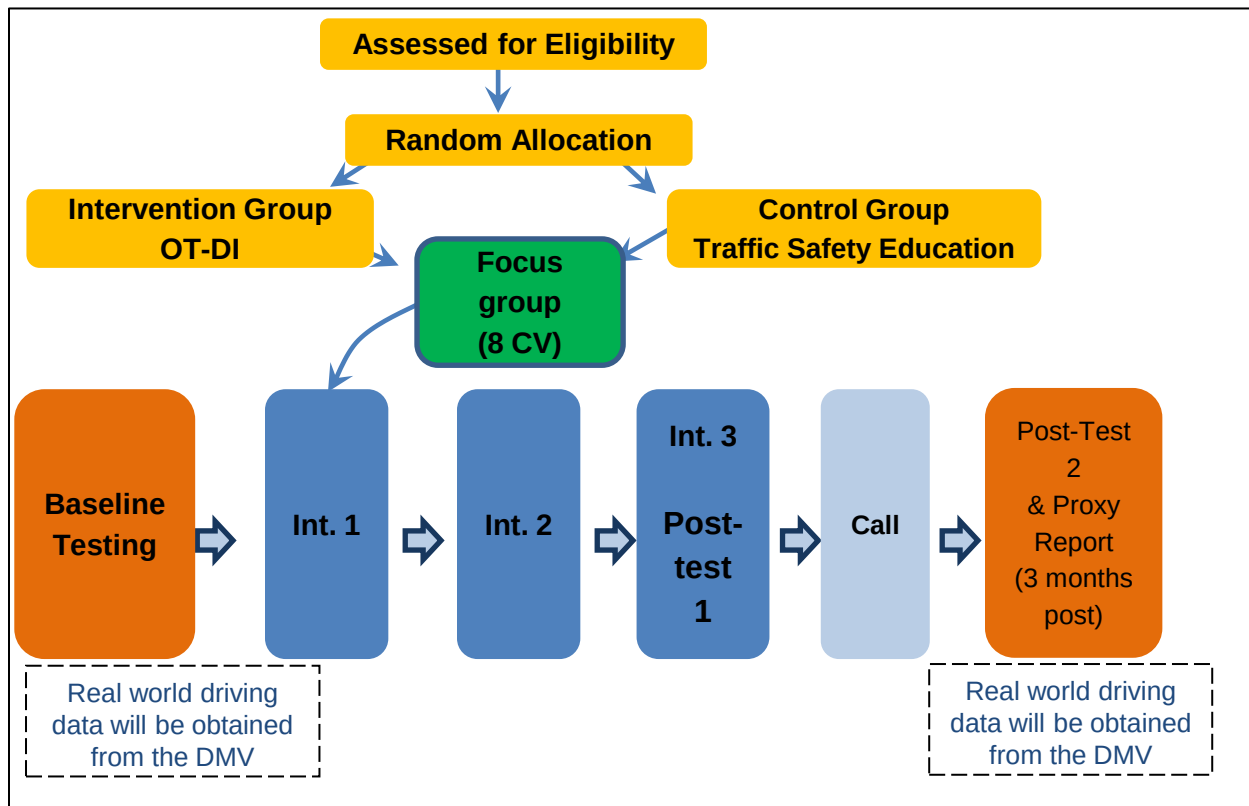
NCT02764983

- Registered with Clinicaltrials.gov

Methods

Design: Multiphase Sequential Mixed Methods Design

- Unblinded parallel arm randomized controlled design



Methods

Study Arms

Intervention group

This group received Occupational Therapy Driving Intervention (OT-DI), consisting of three x 1 hour sessions.

- **Session 1: Coaching** strategies by the driving evaluator to discern the CVs' awareness of driving errors; discuss **adaptation** strategies.
- **Session 2: Visual-search** skills training.
- **Session 3: CV drove simulator while narrating** the drive and receiving targeted feedback.

Control group

This group received, from a Florida state accredited driving safety professional, three x 1 hour general safety sessions.

- **Session 1:** General **traffic safety** discussion.
- **Session 2: Rules of the road** and knowledge of the road discussion.
- **Session 3: Drove the simulator without any feedback** from traffic safety professional.

Katelyn Caldwell, BHS Student

FIDELITY OF A TRAFFIC SAFETY EDUCATION INTERVENTION

Traffic Safety Education

- Method for educating new and experienced drivers
- Basic Driver Improvement Courses
- Current standard of practice
- Mandatory training after certain moving violations



Retrieved from <http://roadnr.com/driver-education-classroom/>

Challenges

- Previously delivered via video
- Threat to fidelity
- No instructors available to film
- Finding a new method of delivery
- Balancing equipoise with feasibility



Retrieved from

http://www.rigzone.com/news/oil_gas/a/140046/the_strengths_challenges_of_investing_in_nigeria/

Selecting a Delivery Method



Retrieved from <http://www.carriersales.com/telecom-partner-program/>

- Six delivery options
- Creation of a comparison chart
- Team discussion and rankings
- Online delivery is best option

Selecting an Online Provider

- National Traffic Safety Institute previously used
- 27 providers
- Narrowed to 5 providers
- Demos
- Consultation
- Handouts vs. videos
- Team discussion
- Driver Training Associates



Retrieved from <https://www.trafficsschool.com/DHSMV-Approved/?dc=FTSCOM>

Implementation Fidelity

- Research Assistant Proctored
- Carroll et al. Framework
 - Adherence to Study Design
 - Quality of Delivery
 - Facilitation Strategies
- Checklist to ensure competency



Retrieved from <https://www.salescoach.us/sales-qualifying-checklist/>

Luther King, DR.OT, CDRS, CDI, OTR/L

RECRUITMENT

Methods

Participants

Recruitment

- Via collaborating sites' networks, flyers, ads, community presentation

Inclusion criteria

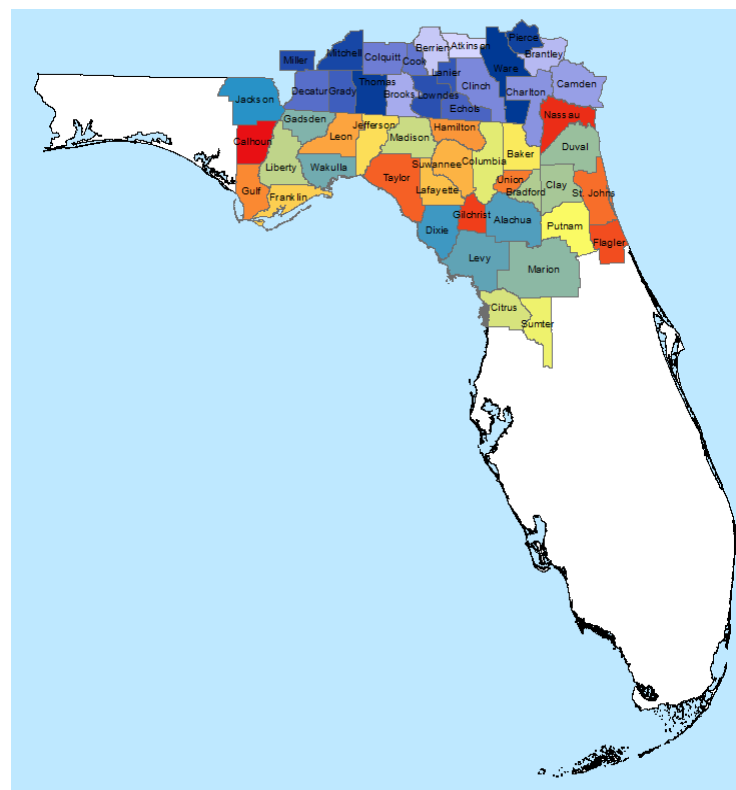
- OIF/OEF/OND CVs with reported driving difficulties
- Valid driver's license/eligible for a driver's license
- Community dwelling
- 24/30 on Mini-Mental State Examination (MMSE)

Exclusion criteria

- CVs with severe psychiatric (e.g., psychoses) or physical conditions (e.g., multiple amputee) that limit their ability to drive
- Advised not to drive by a physician
- Severe, irremediable medical conditions (e.g., severe TBI) as per the consulting physician
- Pregnant females or those planning pregnancy
- VA employees

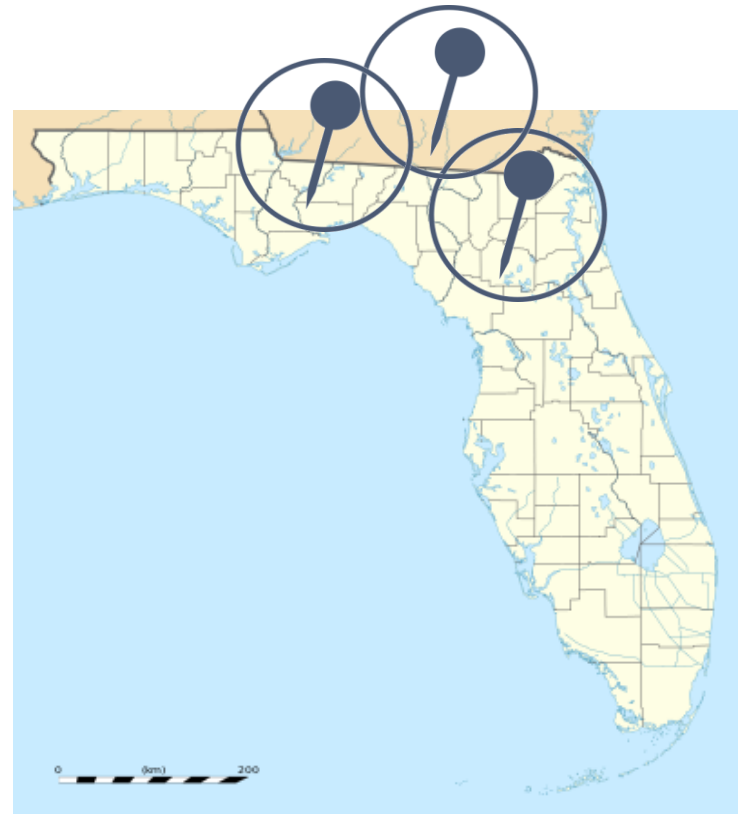
Area

North Florida/South Georgia



Recruitment Locations

- Veteran Administration Hospitals
- Community Based Outpatient clinics
- Domicile centers
- Secondary education entities
- Veteran Administration outreach services



Recruitment Outreach Methods

- Flyer postings
- Emails
- Phone calls
- Presentations
- Attendance/Presence at sponsored events for Veterans
- Personal appearances
- Follow-up with previously established contacts



Recruitment Tug-of-War

Challenges

- Making contact with Veteran Administration entities
- Obtaining follow through from Veteran Administration entities
- Time constraints of Veteran clinicians
- Time constraints of the Veteran



Successes

- Creative ways of outreach
- Developed relationships
- Increased awareness of Veteran Administration clinicians of the needs of their clients regarding driving
- Increased enrollment in study

Recruitment Enrollment

- Interested Veterans can call the study line 352-273-6024



Sherrilene Classen, PhD, MPH, OTR/L, FAOTA, FGSA

METHODS AND RESULTS

Methods

Sample size calculations

- $\alpha = .05$
- $\beta = 20\%$
- Effect size = .4
- Sample size = 60 (30 subjects per group)

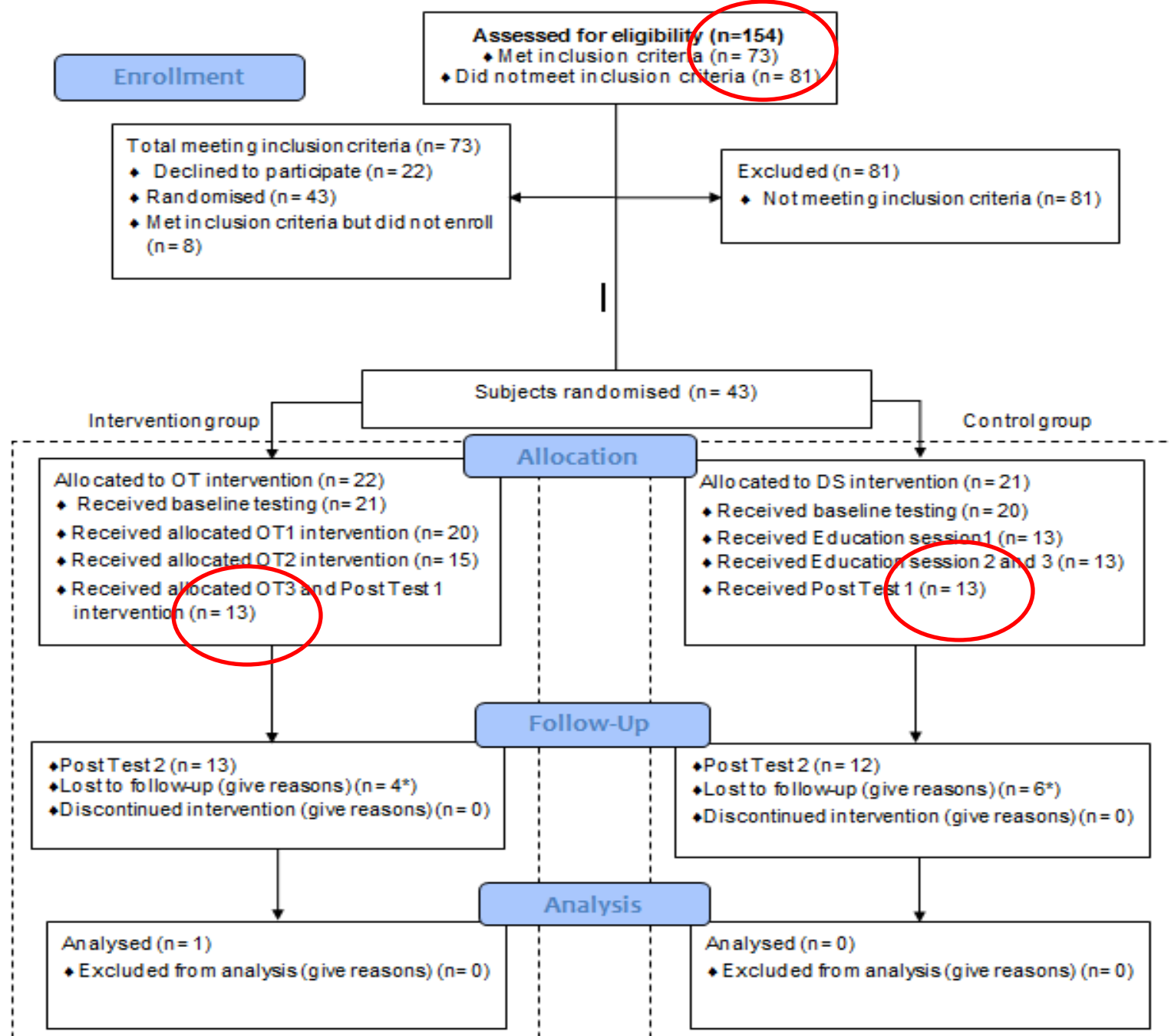
Randomization sequence

Computer-generated block ($\times 6$) randomization scheme for random allocation of participants to either an intervention or control group



CONSORT Diagram (Subjects)

N=26 (60)



Methods

Measures: Ind. Variables

Demographic questionnaires

- Physical Health Information
- Blast Exposure History
- Driving History
- Medical Questionnaire
- Medications Questionnaire

Proxy measure^{1,2,4}

- Fitness-to-Drive Screening Measure

Clinical Driving Assessments

- Simulator Sickness Questionnaire
- Visual, Cognitive, Motor
- Propensity for Angry Driving Scale
- Community Integration Questionnaire
- Satisfaction with Life Questionnaire

-
1. Classen, S. (2014). OTJR
 2. Classen, S. (2014). AJOT
 4. Classen, S. (2011). AJOT

Methods

VA Mobile DriveSafety CDS-250 Driving Simulator

Measures: Outcome Variable

- Targeted simulator scenarios
- High-fidelity CDS 250 driving simulator
- Standardized driving assessment tool
- Three trained DRS⁵

ICC: 99.3% city/highway

98% suburban/residential

Driving Errors⁶

- Visual scanning errors
- Lane maintenance errors
- Speeding errors
- Vehicle positioning errors
- Adjustment-to-stimuli errors
- Signaling errors
- Gap acceptance errors
- Total number of driving errors



Dodge Sprinter van with the CDS-250



5. Classen, S. et al. (2015) ATS

6. Classen, S. et al. (2010) AJOT

Video of Drives

Video 1

- Residential: Swerving motor cycle noise



DriveSafety_drive 1 draft.mp4

Video 2

- City: Trash bag, Speeding, Crash



DriveSafety_Drive 2.mp4

Methods

Data Collection and Analysis

SPSS Statistics for Windows, Version 22.0. (Armonk, NY: IBM Corp.)

- Descriptive statistics (M , SD ; #; %)
- Shapiro Wilks test for normality of distribution
- Wilcoxon rank-sum test for (OT-DI and TSE) driving errors
- A1, A2, A3, A4
 - Within group differences
 - Between group differences

Results

Descriptive statistics of IV

- Late **30's**
- **Male**
- Mostly **White**
- Majority have **education > high school**
- Majority **married**
- **40% IG, 25% CG** reported ≥ 1 **crashes** in the past 3 years
- **30% IG, 58% CG** reported ≥ 1 **driving citation** in the past 3 years
- Both groups had similar **combat-related exposures**

The findings suggest no SS differences between the IG and CG

Demographics statistics for the returning CV (N=26) by Intervention (n=13) and Control (n=13) groups.

Demographics	Intervention group (n=13), Freq. (%) or M (SD)	Control group (n=13), Freq. (%) or M (SD)
Age, M(SD)	38.69 (± 6.52)	37.31 (± 10.21)
Gender		
Male	13 (100.0%)	13 (100.0%)
Race		
White	13 (100.0%)	8 (61.5%)
Other	0	5 (38.5%)
Ethnicity		
Hispanic or Latino	2 (15.4%)	2 (15.4%)
Not Hispanic	11 (84.6%)	11 (84.6%)
Educational Level		
Completed High school and lower	2 (15.4%)	2 (15.4%)
Greater than High school	11 (84.6%)	11 (84.6%)
Marital Status		
Married	10 (76.9%)	8 (61.5%)
Others	3 (23.1%)	5 (38.5%)
Living Status		
Alone	3 (23.1%)	2 (15.4%)
With someone	10 (76.9%)	11 (84.6%)
Number of crashes in the past 3yrs.		
None	6 (60.0%)	9 (75.0%)
1 or more	4 (40.0%)	3 (25.0%)
Number of citations in the past 3yrs.		
None	7 (70.0%)	5 (41.7%)
1 or more	3 (30.0%)	7 (58.3%)
Mortar		
Yes	8 (61.50)	8 (61.50)
No	5 (38.5)	5 (38.5)
Improvised explosive device		
Yes	8 (61.5)	5 (38.5)
No	5 (38.5)	8 (61.5)

Results

Descriptive Statistics of OV

- **IG**: Reduction in all driving errors
- **CG**: Reduction in all driving errors, except gap acceptance
- Total Driving Errors

IG: 42% ; CG 8%

DRS 30%

Mean and standard deviation for driving errors at baseline and post-test 1 for combat veterans' (N=26) by Intervention (n=13) and Control (n=13) groups.

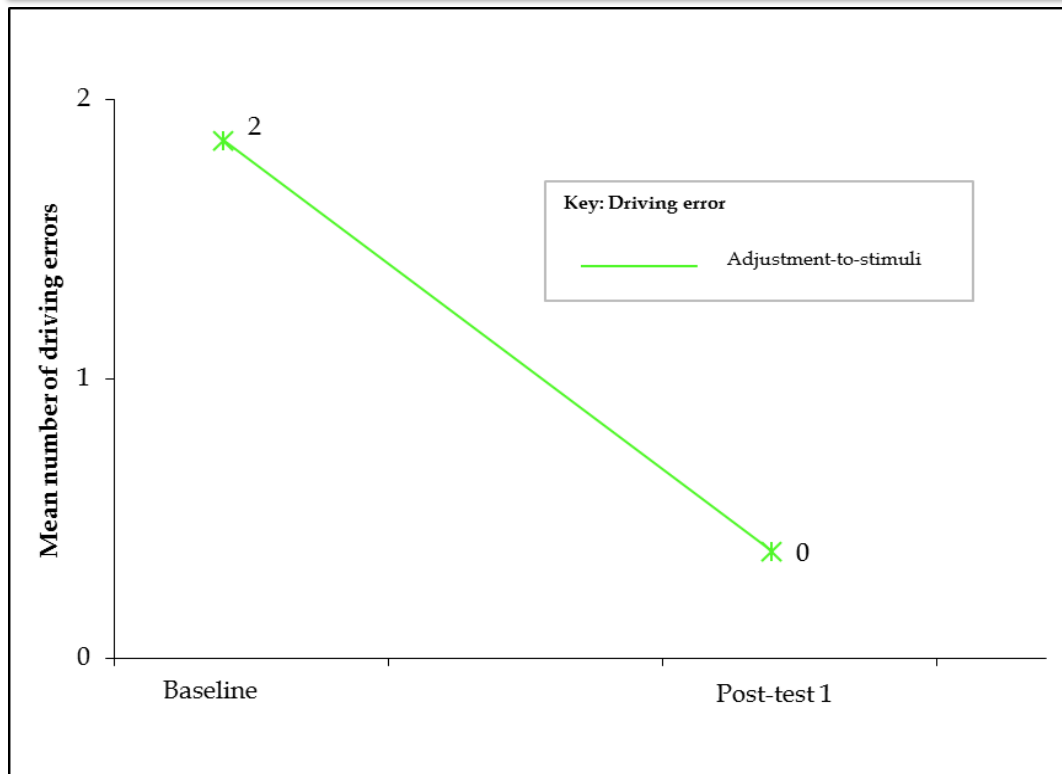
Legend: M: Mean, SD: Standard deviation

Driving error type	Intervention group		Control group	
	Baseline	Post-test 1	Baseline	Post-test 1
	M (SD)	M (SD)	M (SD)	M (SD)
Speeding	12.31 (7.40)	4.92 (4.09)	13.00 (7.81)	10.08 (7.30)
Lane maintenance	12.23 (5.78)	6.15 (4.51)	9.92 (5.57)	8.69 (5.21)
Vehicle positioning	2.38 (1.89)	0.62 (0.65)	1.85 (1.68)	1.15 (1.14)
Gap acceptance	2.08 (1.04)	1.23 (1.30)	2.07 (1.32)	2.46 (1.05)
Signaling	1.62 (1.66)	0.38 (0.87)	3.08 (3.20)	2.54 (3.26)
Adjustment-to-stimuli	1.46 (2.26)	0.46 (0.78)	1.54 (1.39)	0.38 (0.51)
Visual scanning	0.38 (0.65)	0.00 (0.00)	0.54 (0.88)	0.15 (0.38)
Total driving errors	32.46 (11.60)	13.77 (9.44)	32.00 (12.41)	25.46 (13.26)

Results

A1: Control baseline vs. Control post-test 1

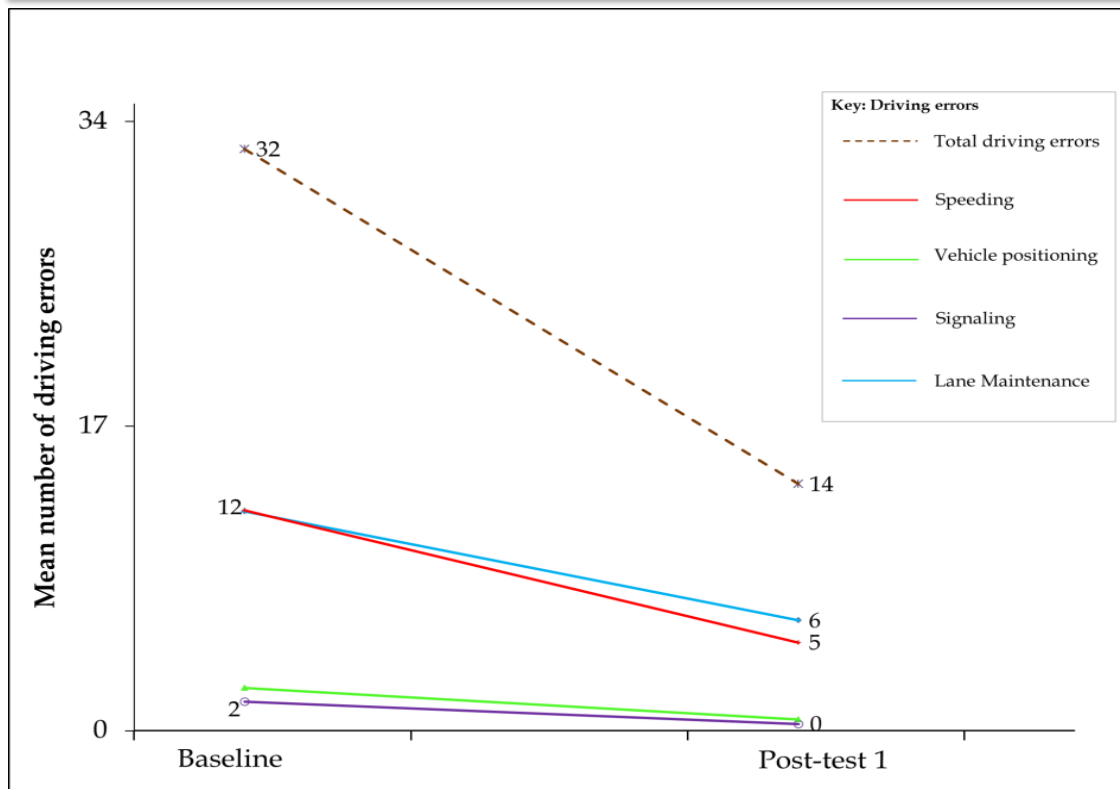
Driving error trend line: Comparison between Control baseline vs. Control post-test 1



Results

A2: Intervention baseline vs. Intervention post-test 1

Driving error trend line: Comparison between Intervention baseline vs. Intervention post-test 1



Total # Driving Errors

Lane maintenance

Speeding

Vehicle positioning

Signaling

Results

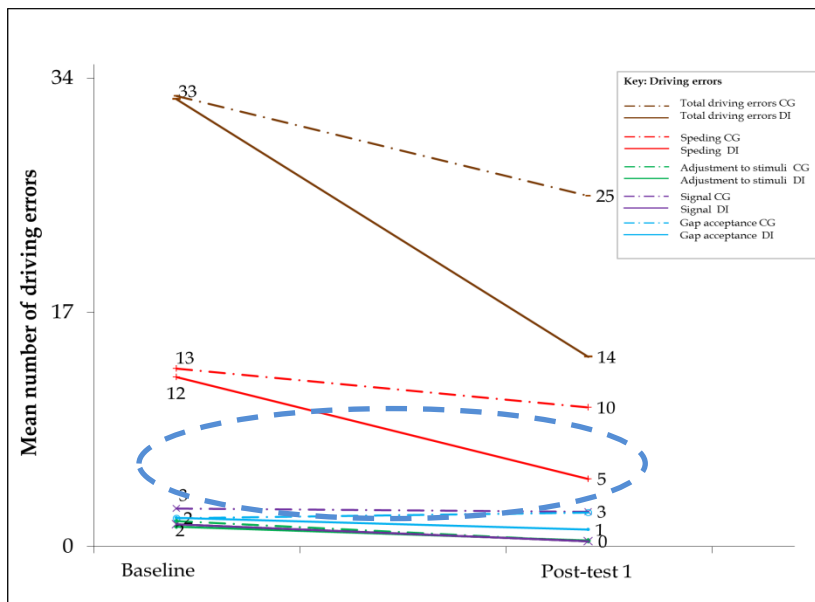
A3: Intervention Baseline vs Control Baseline:

No statistical significance

Results

A4: Intervention post-test 1 vs Control post-test 1

Driving error trend line: Comparison between Intervention post-test 1 vs Control post-test 1

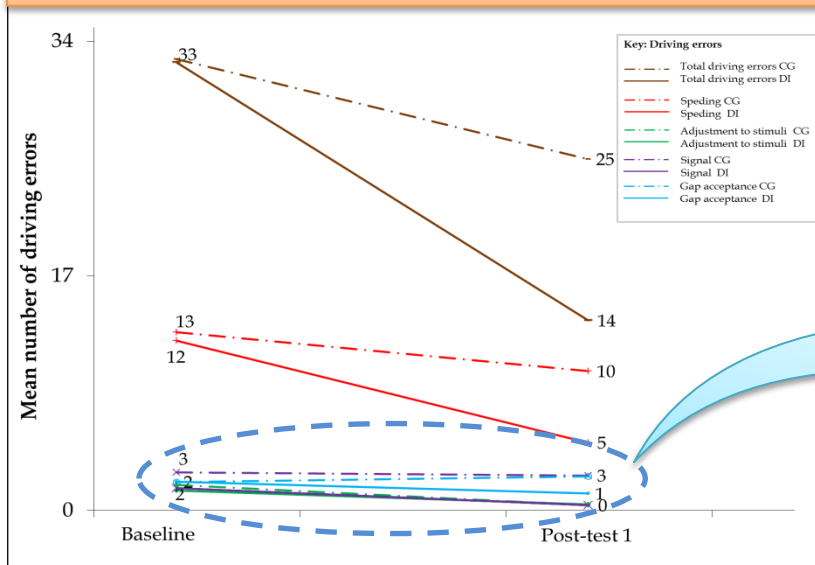


Total # Driving Errors
Speeding

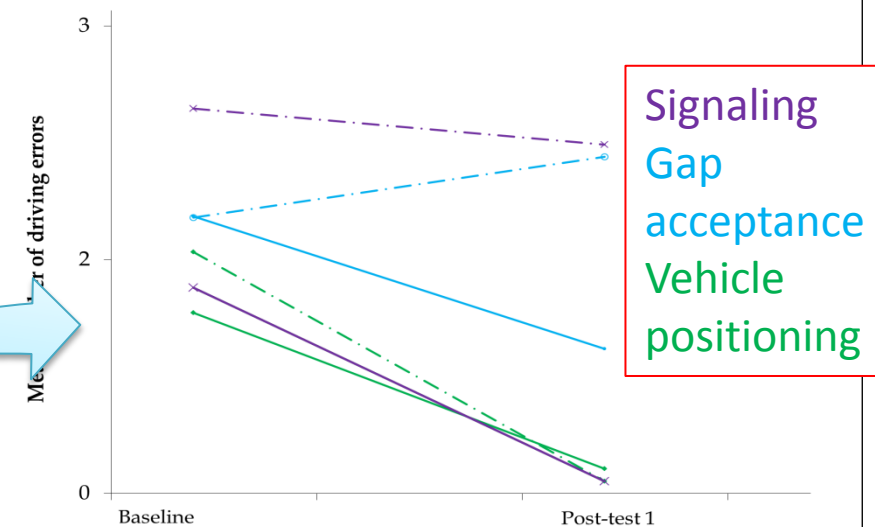
Results

A4: Intervention post-test 1 vs Control post-test 1

Driving error trend line: Comparison between Intervention post-test 1 vs Control post-test 1



Driving error trend line: Comparison between Intervention post-test 1 vs Control post-test 1



Results

Group comparison

Within and Between-Group Differences in Driving Errors at Baseline and Post-Test 1 for Combat Veterans (N = 26) by Intervention (n = 13) and Control (n = 13) Groups.

Analysis	Test statistic	Visual scanning	Lane maintenance	Speeding	Vehicle positioning	Adjustment-to-stimuli	Signaling	Gap	Total driving errors
A1	W	159.50	167.00	151.00	156.50	126.50	166.50	161.50	145.00
	M (SD)	0.35(0.69)	9.31 (5.33)	11.54 (7.56)	1.50 (1.45)	0.96 (1.18)	2.81 (3.18)	2.27 (1.19)	28.73 (13.02)
	p-value	.26	.68	.22	.33	.01	.65	.48	.12
A2	W	149.50	125.00	127.00	130.00	152.00	128.00	145.50	110.00
	M (SD)	0.19(0.49)	9.20 (5.94)	8.62 (6.96)	1.50(1.65)	0.96 (1.73)	1.00 (1.44)	1.65 (1.23)	23.12 (14.08)
	p-value	.10	.01	.01	.01	.20	.01	.11	< .001
A3	W	171.50	151.00	173.50	162.00	158.00	157.00	169.50	172.00
	M (SD)	0.46(0.76)	11.08 (5.68)	12.12 (7.46)	2.12 (1.77)	1.50 (1.84)	2.35 (2.61)	2.08 (1.16)	32.32 (11.77)
	p-value	.83	.22	.93	.50	.39	.35	.77	.87
A4	W	162.50	153.00	137.50	154.50	174.00	125.00	131.50	126.00
	M (SD)	0.08(0.27)	7.42 (4.95)	7.50 (6.36)	0.88 (0.95)	0.42 (0.64)	1.46 (2.58)	1.84 (1.32)	19.62 (12.76)
	p-value	.48	.26	.05	.31	.05	< .001	.02	.01

Legend:

A1: Control baseline vs. Control post test 1

A3: Control baseline vs. Intervention baseline

A2: Intervention baseline vs. Intervention post test 1

A4: Control post test 1 vs. Intervention post test 1

Summary

- Participants in this study were male, mainly white and educated.
- Both groups at baseline made similar driving errors.
- **Clinical significant differences**
 - Reduction in mean number of total driving errors for both groups from Baseline to Post-test 1.
- **Statistical significant differences**
 - **A1:** IG had a reduction across five driving errors from B → to PT1.
 - **A2:** CG had a reduction in adjustment-to-stimuli errors from B → PT1.
 - **A3:** No significant finding in comparing IG B with CG B.
 - **A4:** IG had a reduction of five driving errors compare to the CG Post-test 1 results.
- The **IG benefited from the OT-DI** whilst the **CG benefited some from the TSE** sessions.
- Sample size (N=26) for this **study was small**, hence caution should be exercised with **generalization**.

Discussion

Limitations

- Lack of **blinding** for DRS → **bias**
- The use of **video** to deliver the TSE content versus in-person delivery → **Hawthorne effect**
 - i.e., observation, or lack thereof, affects performance
- Driving scenarios used at baseline and post-tests were the same and the **scripted events were not randomized** → **learning effect**
- Delay in Post-test 2 for CG → **internal validity**

Discussion

Strengths

- This study followed a **blocked randomization scheme** to allocate participant to control and intervention groups.
- At **baseline**, group participants were **not significantly different** in demographics, exposures and driving errors.
- In addition to analysing intervention efficacy, our study design allowed us to **improve the feasibility** of the intervention.

Discussion

Practice Implications

- This study illustrates **early empirical support** for a simulator-based **OT-DI** focusing on veterans' driving performance.
- The **evidence-informed driving simulator protocol** will help **OTs** inside and outside of VA and military settings to evaluate and treat driving performance deficits in CV.